| **DRUG, SPONSOR, TYPE OF SUBMISSION** | **DRUG TYPE OR USE** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** |
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| **ADALIMUMAB**  20 mg/0.4 mL injection, 2 x 0.4 mL syringes  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    Humira®    AbbVie Pty Ltd  Change to listing  (Major submission) | Paediatric Crohn Disease | Authority Required listing for the treatment of paediatric Crohn disease in patients who meet certain criteria. | The PBAC recommended extending the current Section 85 listing of adalimumab to include listing for the treatment of severe refractory Crohn disease in paediatric patients aged 6 to 17 years. The PBAC recommended an Authority required (written-only) restriction for both initial and continuing treatment.  The PBAC recommended the listing of adalimumab on a cost-minimisation basis with infliximab. The PBAC considered the equi-effective doses are:   * adalimumab – patients weighing less than 40 kg: 80 mg at week 0, 40 mg at week 2, then 20 mg every other week thereafter; patients weighing more than or equal to 40 kg: 160 mg at week 0, 80 mg at week 2, then 40 mg every other week thereafter; and * infliximab – 5 mg/kg at weeks 0, 2, 6 and every 8 weeks thereafter. |
| **AFLIBERCEPT**  4 mg/0.1 mL injection, 1 x 0.1 mL vial  4 mg/0.1 mL injection, 1 x 0.90 mL syringe  Eylea®  Bayer Australia Ltd  Change to listing  (Major submission) | Diabetic Macular Oedema | Authority Required listing for the treatment of diabetic macular oedema. | The PBAC recommended extending the listing of aflibercept as Section 85 Authority Required benefit to include treatment of a patient with visual impairment due to diabetic macular oedema. The PBAC considered that Authority applications through the PBS and Specialised Drugs Branch of the Department of Human Services would be appropriate for aflibercept, similar to administrative arrangements for ranibizumab and aflibercept in age-related macular degeneration (AMD).  The PBAC recommended the listing of aflibercept on a cost-minimisation basis with ranibizumab. The PBAC determined that the equi-effective doses are aflibercept 2 mg injection : 0.5 mg ranibizumab injection.  The PBAC also considered aflibercept to be non-inferior to bevacizumab in terms of effectiveness and safety, at equi-effective doses of aflibercept 2 mg injection: 1.5 mg bevacizumab injection. The PBAC noted the bevacizumab equi-effective dose for this submission is different with the submission for aflibercept for central retinal vein occlusion (CRVO) also considered on the November 2014 agenda. The PBAC considered that this was due to the different trial data available for bevacizumab for each indication.  On the basis of direct evidence presented by the submission, for patients treated with aflibercept there would be:   * approximately a 10.01 letter gain in best corrected visual acuity (BCVA) for aflibercept when compared to laser photocoagulation over a 12 month duration of follow-up.   On the basis of the indirect comparison of aflibercept with ranibizumab, there would be:   * approximately a 4.81 letter gain in BCVA for aflibercept when compared to ranibizumab over a 12 month duration of follow-up. However, this difference may be an artefact of the difference in trial populations and does not represent a clinically significant improvement in vision-related quality of life.   On the basis of the indirect comparison presented, the frequency of adverse effects over 12 months appears to be similar for patients treated with either aflibercept or ranibizumab.  On the basis of the information provided, there appears to be no difference in benefits and harms between aflibercept in comparison to bevacizumab. |
| **AFLIBERCEPT**  4 mg/0.1 mL injection, 1 x 0.1 mL vial  4 mg/0.1 mL injection, 1 x 0.90 mL syringe  Eylea®  Bayer Australia Ltd  Change to listing  (Major submission) | Macular Oedema secondary to central retinal vein occlusion | Authority Required listing for the treatment of central retinal vein occlusion. | The PBAC recommended extending the listing of aflibercept as Section 85 Authority required benefit to include treatment of a patient with macular oedema due to central retinal vein occlusion (CRVO). The PBAC considered that authority applications through the PBS and Specialised Drugs Branch of the Department of Human Services would be appropriate for aflibercept, similar to administrative arrangements for ranibizumab and aflibercept in age-related macular degeneration (AMD).  The PBAC recommended the listing of aflibercept on a cost-minimisation basis with ranibizumab. The PBAC determined that the equi-effective doses are aflibercept 2 mg injection : 0.5 mg ranibizumab injection.  The PBAC also considered aflibercept to be non-inferior to bevacizumab in terms of effectiveness and safety, at equi-effective doses of aflibercept 2 mg injection : 1.25 mg bevacizumab injection. The PBAC noted the bevacizumab equi-effective dose for this submission is different with the submission for aflibercept for diabetic macular oedema (DME) also considered on the November 2014 agenda. The PBAC considered that this was due to the different trial data available for bevacizumab for each indication.  On the basis of the indirect evidence using sham injection as the common reference, there appears to be no difference in benefits and harms between aflibercept in comparison to ranibizumab or bevacizumab. |
| **ANAKINRA**  100 mg/0.67 mL, 28 x 0.67 mL syringes  Kineret®  A.Menarini Australia Pty Ltd  New listing  (Major submission) | Cryopyrin Associated Periodic Syndromes | Section 100 Authority Required listing for the treatment of cryopyrin-associated periodic syndromes. | The PBAC recommended the listing of anakinra for the treatment of moderate to severe cryopyrin-associated periodic syndromes (CAPS) under the Section 100 Highly Specialised Drugs Program (HSDP) on the basis of acceptable cost-effectiveness compared to best supportive care.  The PBAC noted that CAPS is a rare condition for which anakinra had been designated by the TGA as an orphan drug for the CAPS indication and that there are currently no drugs listed on the PBS for the specific treatment of CAPS. The consumer comments received in support of anakinra reflected this gap in treatment and the PBAC acknowledged these comments. |
| **ANTI-CANCER DRUGS,**  CAPECITABIINE, tablets, 150 mg and 500 mg  MEGESTROL, tablet, 160 mg  TOREMIFENE, tablet, 60 mg  VINORELBINE, vials for injection, 10 mg/mL injection, 1 x 1 mL vial and 50 mg/5 mL injection, 1 x 5 mL vial,  The Medical Oncology Group of Australia on behalf of various sponsors  Change to listing  (Correspondence) | Cancer | The Medical Oncology Group of Australia sought to have the drugs capecitabine, megestrol, toremifene and vinorelbine (injection presentation only) made available as unrestricted pharmaceutical benefits. | The PBAC had no objections to these four drugs becoming unrestricted benefits on the PBS. |
| **ANTI-CANCER DRUGS,**  ANASTROZOLE, tablet, 1 mg,  EVEROLIMUS, tablets, 5 mg and 10 mg    EXEMESTANE, tablet, 25 mg  GOSERELIN, implant, 3.6 mg  LETROZOLE, tablet, 2.5 mg  The Medical Oncology Group of Australia on behalf of various sponsors  Change to listing  (Correspondence) | Cancer | The Medical Oncology Group of Australia sought to have the drugs anastrozole, everolimus, exemestane, goserelin and letrozole made available to males with breast cancer | The PBAC recommended amending the restrictions for these five drugs and their breast cancer indications in such a way that male patients are not precluded from access to subsidy. |
| **APOMORPHINE HYDROCHLORIDE**  10 mg /1 mL injection: 5 x 1 mL ampoules,  Apomine®  Hospira Pty Ltd  New listing  (Minor submission) | Parkinson disease | Section 100 Authority Required listing of a lower strength for the management of advanced Parkinson disease. | The PBAC recommended listing under the same conditions as the existing listing for the 20 mg in 2 mL presentation. |
| **AXITINIB**  tablets, 1 mg & 5 mg,  Inlyta®  Pfizer Australia Pty Ltd  New listing  (Major submission) | Renal cell carcinoma | Authority Required listing for the treatment of Stage IV clear cell variant renal cell carcinoma in patients meeting certain criteria. | The PBAC recommended listing axitinib as an Authority Required benefit for the treatment of Stage IV clear cell variant renal cell carcinoma (RCC) in a patient with a WHO performance status of 2 or less, after failure of prior PBS-subsidised first-line treatment for this condition, on a cost-minimisation basis with everolimus. The equi-effective doses are axitinib 5 mg twice daily and everolimus 10 mg once daily.  The PBAC acknowledged the clinical need for having an alternative option for second line therapy in the treatment of RCC as conveyed by the European Society for Medical Oncology (ESMO) clinical practice guidelines and in the sentiment expressed in the consumer comments. The PBAC noted in particular that various consumer comments appeared to convey an unrealistic expectation that axitinib would offer a curative treatment option and was concerned that this expectation was not in accord with the results of the clinical evidence presented. The PBAC observed that the reported PFS for patients treated with axitinib was 4.8 months compared with 4.6 months for everolimus in the naïve side by side comparison. |
| **BUPRENORPHINE + NALOXONE**  4mg/1mg film: sublingual, 12mg/3mg film: sublingual,  Suboxone® sublingual film,  Reckitt Benckiser Pty Ltd.  New listing  (Minor submission) | Opiate dependence | Section 100 (Opiate Dependence Treatment Program) listing of two new strengths of buprenorphine + naloxone sublingual film. | The PBAC recommended the listing of two additional strengths of buprenorphine + naloxone (12mg/3mg and 4mg/1mg) on the basis that it provides benefits to both patients and prescribers in relation to the quality use of medicines, namely, that there is a shorter administration time and potential for a decreased risk of diversion, while improving flexibility of dose titration. |
| **CERTOLIZUMAB PEGOL**  200 mg/ml injection, 2 x 1 ml syringes  Cimzia®  UCB Australia Pty Ltd  Change to listing  (Major submission) | Psoriatic arthritis | Authority Required listing for the treatment of patients with severe active psoriatic arthritis who meet certain criteria. | The PBAC recommended an Authority Required benefit listing of certolizumab pegol (CZP) for the treatment of psoriatic arthritis on the cost-minimisation basis with adalimumab (ADA), at the sponsor’s proposed price. The equi-effective doses are CZP 400mg at weeks 0, 2, 4 followed by 200mg every 2 weeks or 400mg every 4 weeks equal to ADA 40mg every 2 weeks. |
| **CETUXIMAB**  100 mg/20 mL injection, 1 x 20 mL vial  500 mg/100 mL injection, 1 x 100 mL vial    Erbitux®    Merck Serono Australia Pty Ltd  Change to listing  (Major submission) | Colorectal cancer | Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first line treatment of metastatic colorectal cancer in patients who meet certain criteria. | The PBAC recommended extending cetuximab’s existing listing to include first-line treatment of metastatic colorectal cancer on a cost-minimisation basis compared with bevacizumab. The equi-effective doses are cetuximab 8,356 mg and bevacizumab 4,229 mg. The availability of first-line cetuximab in the PBS would increase choices of first-line treatment for patients with a RAS wild type status.  The PBAC recalled that the amendment of cetuximab later-line restriction from KRAS WT to RAS WT status was recommended at its July 2014 meeting when recommendation for the equivalent amendment of panitumumab PBS restriction was made.  The PBAC considered that the requested restriction should 1) include a note stating “Patient must not switch chemotherapy partners whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease” in order to help prevent cetuximab being used beyond disease progression; 2) amend WHO performance status to be 1 or less; 3) limit use to a course of cetuximab for mCRC once in a life time (and allow a switch to panitumumab during a course only according to the arrangements already in place for PBS subsidy of later-line therapy); 4) indicate anti-EGFR antibody and anti-VEGF antibody cannot be used at the same time. |
| **COAL TAR PREPARED**  foam aerosol, 2% (20 mg/g), 100 g,  Scytera® Foam  Dr Reddy’s Laboratories Australia Pty Ltd  New Listing  (Minor submission) | Psoriasis | Unrestricted benefit listing. | The PBAC recommended the listing of coal tar prepared 2% foam as an unrestricted benefit for the treatment of psoriasis based on the equi-effectiveness of 1 g of Scytera® (coal tar prepared 2% 10 mg/g foam, 100 g.) to 1 mL of Exorex™(coal tar prepared 1% 10 mg/g lotion, 100 mL.). |
| **CRIZOTINIB**  capsules, 200 mg and 250 mg,    Xalkori®    Pfizer Australia Pty Ltd  New listing  (Minor submission) | Non-small cell lung cancer | To address key issues raised in the March 2014 PBAC deferral of crizotinib for the treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer. | The PBAC recommended the Authority Required listing of crizotinib for the treatment of locally advanced or metastatic non-small cell lung cancer patients with an anaplastic lymphoma kinase (ALK) gene rearrangement in their tumour material, on the basis of acceptable cost-effectiveness over pemetrexed to be achieved in the context of a managed entry framework. The PBAC noted that the incremental overall survival gain for crizotinib over pemetrexed is uncertain (overall survival gain of 3.1 – 3.5 months observed in the clinical trials versus 12 months as claimed by the submission). The PBAC recognised the clinical need for crizotinib being available for the treatment of patients with ALK-positive locally advanced or metastatic non-small cell lung cancer.   * The initial entry price for the managed entry scheme (MES) would be as requested by the submission. The MES framework would include a mechanism for payment of a rebate with interest to the Commonwealth should crizotinib fail to deliver on its claimed benefits. On submission of new information as outlined below, there would be no option for an increase in price of crizotinib, as the higher price would already have been paid since entry onto the PBS. * The possible outcomes following consideration of the new information in the MES would be that either: * the price of crizotinib would reduce; or * the price of crizotinib would be maintained. * The Commonwealth would bear the upfront risk associated with the uncertain clinical benefit. Accordingly, should this modelled extent of benefit not be realised with reference to the information outlined below, then the sponsor would rebate the Commonwealth to the effect of: * the ensuing price reduction required to meet the same ICER with reduced clinical benefits, multiplied by; * the number of PBS-dispensed prescriptions of crizotinib between the date of listing and the date of implementation of the price reduction, and after applying; * an interest rate deemed appropriate by the Commonwealth. * The new information requested is the proportion of the first 50 consecutive patients to start therapy with crizotinib after any PBS listing begins (i.e. excluding patients who are continuing therapy with crizotinib already started before any PBS listing begins) who are alive 365 days after starting therapy with crizotinib. * This result would be provided as soon as possible after the 50th consecutive patient has been followed for 365 days. This sample size was proposed on the expectation that, with the estimated number of incident patients, it would take approximately two years to generate the data. * To address the greater uncertainty of the overall survival following pemetrexed being underestimated by the model, there would be a 1% increase in the modelled proportion of pemetrexed patients who are alive at day 365 for every 1% that the observed PBS result is below the trial estimate. This uncertainty is primarily due to the cross-over to crizotinib in the pemetrexed arm of the trial following a progression event. |
| **DAPAGLIFLOZIN**  10 mg tablet, 28  Forxiga®  AstraZeneca Pty Ltd  Change to listing  (Major submission) | Diabetes mellitus type 2 | Extend the current Authority Required listing to include the treatment of diabetes mellitus type 2, in combination with insulin, in patients who meet certain criteria. | The PBAC recommended the listing of dapagliflozin 10 mg tablets for the treatment of type 2 diabetes in combination with insulin. The recommendation was formed on the basis of a cost-minimisation and cost analysis to up-titrated insulin. |
| **DIPHTHERIA  + TETANUS + ACELLULAR PERTUSSIS (dTPa) VACCINE**    Infanrix®    GlaxoSmithKline Australia Pty Ltd  Change to listing  (Major submission) | Immunisation against pertussis | Inclusion of an additional booster dose of DTPa on the National Immunisation Program (NIP) at 18 months of age. | The PBAC recommended including an 18-month booster dose of the combined diphtheria, tetanus and acellular pertussis (DTPa) vaccine on the National Immunisation Program (NIP) for the prevention of pertussis on the basis of cost‑effectiveness compared with the current schedule without the booster. The PBAC agreed with the Australian Technical Advisory Group on Immunisation (ATAGI) that there is a public health need to improve suboptimal control of pertussis.  On the basis of a dynamic transmission model of the whole Australian population, for every 100,000 persons vaccinated, if the 18-month DTPa booster vaccination is included in the immunisation schedule in comparison to ‘no booster’ (the current schedule) per year:   * Approximately 262 fewer persons would have a non-notified case of pertussis. * Approximately 7 fewer persons would have a notified case of pertussis. * Approximately 0.4 fewer persons would be hospitalised due to pertussis. |
| **DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE**  dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30    Triumeq®    ViiV Healthcare Pty Ltd  New listing  (Major submission) | HIV Infection | Section 100 Authority Required listing for the treatment of HIV infection in patients meeting certain criteria. | The PBAC recommended Section 100 (Highly Specialised Drugs Program) listing of dolutegavir+lamivudine+abacavir (Triumeq FDC). The PBAC recommended the special arrangements under the Highly Specialised Drugs Program, Private Hospital Authority Required and Public Hospital Authority Required (STREAMLINED).  The PBAC recommended the listing of Triumeq on a cost-minimisation basis with emtricitabine+tenofovir+efavirenz (Atripla FDC) for the treatment of patients with HIV. The equi-effective doses are dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg from one Triumeq tablet is equal to tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg from one Atripla tablet. |
| **ENOXAPARIN SODIUM**  20 mg/0.2 mL injection, 10 x 0.2 mL pre-filled syringes  40 mg/0.4 mL injection, 10 x 0.4 mL pre-filled syringes  60 mg/0.6 mL injection, 10 x 0.6 mL pre-filled syringes  80 mg/0.8 mL injection, 10 x 0.8 mL pre-filled syringes  100 mg/1 mL injection, 10 x 1 mL pre-filled syringes    Clexane Safety-Lock®    Sanofi-Aventis Australia Pty Ltd.  New listing  (Minor submission) | Prevention of blood clots | To request listing of a new presentation of safety-lock pre‑filled syringes on the PBS | The PBAC recommend listing on the PBS on the basis that the new formulation is equivalent to the currently PBS-listed enoxaparin (Clexane®) for all available strengths and indications.  The PBAC recommended enoxaparin (Clexane Safety-Lock®) and enoxaparin (Clexane®) should be considered equivalent for the purposes of substitution. |
| **EZETIMIBE+ATORVASTATIN**  ezetimibe 10 mg + atorvastatin 10 mg tablet, 30  ezetimibe 10 mg + atorvastatin 20 mg tablet, 30  ezetimibe 10 mg + atorvastatin 40 mg tablet, 30  ezetimibe 10 mg + atorvastatin 80 mg tablet, 30    Atozet®    Merck Sharp and Dohme (Australia) Pty Ltd  New listing  (Major submission) | Hypercholesterolaemia | Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia in patients who meet certain criteria. | The PBAC recommended listing the fixed dose combination tablets for the same Authority Required (STREAMLINED) listings as applying to the existing composite packs, on a cost-minimisation basis with the individual components taken concomitantly. It was noted that the fixed dose combination tablets would replace the composite packs. |
| **GLUCOSE INDICATOR BLOOD**  glucose indicator blood strip: diagnostic, 100    Dario® Blood Glucose Test Strip  uHealth Australia Pty Ltd  New listing  (Minor submission) | Diabetes | Unrestricted benefit listing and restricted benefit listing for blood glucose monitoring. | The PBAC recommend listing under the same conditions as currently listed PBS‑listed blood glucose test strips. |
| **GLUCOSE INDICATOR BLOOD**  glucose indicator blood strip: diagnostic, 50 and 100    GluNeo® Blood Glucose Test Strip  Infopia Australia Pty Ltd  New listing  (Minor submission) | Diabetes | Unrestricted benefit listing and restricted benefit listing for blood glucose monitoring. | The PBAC recommend listing under the same conditions as currently listed PBS‑listed blood glucose test strips. |
| **GLUCOSE INDICATOR BLOOD**  glucose indicator blood strip: diagnostic, 50 and 100    Healthpro® Blood Glucose Test Strip  Infopia Australia Pty Ltd  New listing  (Minor submission) | Diabetes | Unrestricted benefit listing and restricted benefit listing for blood glucose monitoring. | The PBAC recommend listing under the same conditions as currently listed PBS‑listed blood glucose test strips. |
| **IRON CHELATING AGENTS**  **DEFERASIROX**, tablets, 125 mg, 250 mg, 500 mg  Exjade®  Novartis Pharmaceuticals Australia Pty Ltd  **DEFERIPRONE**, oral liquid, 100 mg/mL, 250 mL, tablet, 500 mg  Ferriprox®  Orphan Australia Pty Ltd,  **DESFERRIOXAMINE**, injections, 2 g vial and 500 mg vials  Desferal®  Novartis Pharmaceuticals  Hospira brand product  Hospira Pty Ltd  (Review) | Iron chelating agents | To consider if further review of the iron chelating agents is required. Following the update given to the PBAC at its March 2014 meeting on the results of the DUSC analysis on iron chelating agents in February 2014, the PBAC requested further information to inform this decision. | The PBAC considered the findings of the DUSC review of iron chelating agents, noting that the use of deferasirox, in particular 500 mg deferasirox, is much higher than that estimated at the time of PBS listing. The PBAC agreed with the DUSC that a considerable proportion of the PBS utilisation of deferasirox is likely to be for myelodysplastic syndromes (MDS) and that the cost effectiveness of deferasirox in MDS is not known.  The PBAC recommended that the PBS restriction for deferasirox be amended to be restricted to the treatment of chronic iron overload in patients with non-malignant disorders of erythropoiesis. The PBAC also requested that clinical advice be sought on the use of iron chelating agents, in particular deferasirox, in MDS and other malignant haematological diseases associated with chronic transfusions from relevant professional bodies.  The PBAC noted that the sponsor may submit an application to the PBAC to extend the listing of deferasirox to include MDS and other malignant haematological diseases associated with chronic transfusions with evidence to support the clinical efficacy and safety and cost effectiveness in this indication. |
| **IRON SUCROSE**  iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules,  Venofer®  Aspen Pharmacare Australia Pty Ltd  Change to listing  (Minor submission) | Iron deficiency anaemia | To amend the current Authority required listing to be consistent with the current restriction for iron polymaltose. | The PBAC recommended amending the current listing of iron sucrose to be identical to iron polymaltose, on a cost minimisation basis with iron polymaltose. The PBAC considered that iron sucrose and iron polymaltose are equi-effective on a per mg elemental iron basis. |
| **IVACAFTOR**  tablet, 150 mg,  Kalydeco®  Vertex Pharmaceuticals (Australia) Pty Ltd  Change to recommended listing  (Minor submission) | Cystic fibrosis | To request an extension of the PBAC’s previous recommendation for the PBS listing of ivacaftor as a Section 100 (Highly Specialised Drugs Program) benefit for the treatment of cystic fibrosis (CF) in patients aged six years and older who have a G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene to include other gating (class III) mutation in the CFTR gene. | The PBAC recommended to extend the PBAC’s previous recommendation for the PBS listing of ivacaftor as a Section 100 (Highly Specialised Drugs Program) benefit for the treatment of cystic fibrosis (CF) in patients aged six years and older who have a G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene to include other gating (class III) mutation in the CFTR gene. |
| **LEUPRORELIN**  30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack  Lucrin Depot PDS®  AbbVie Pty Ltd  Change to listing  (Major submission) | Central precocious puberty | Extend the current Authority Required (STREAMLINED) listing to include the treatment of central precocious puberty. | The PBAC recommended the listing of leuprorelin for the treatment of children with central precocious puberty (CPP). This is currently widely used in clinical practice with PBS listing providing improved patient access to treatment. On the basis of evidence provided in the submission, for every 100 patients treated, approximately 95 patients would have levels of peak stimulated luteinising hormone suppressed to less than 4mIU/mL, a level which is considered a relevant surrogate treatment outcome. The PBAC considered suppression of the physical signs of puberty to be a more patient relevant outcome. For every 100 female patients treated with leuprorelin, approximately 71 would have suppression of puberty, while for every 100 male patients treated, approximately 20 would have suppression of puberty. |
| **MERCAPTOPURINE**  oral suspension 20 mg/mL, 100 mL  Allmercap®  Link Healthcare Pty Ltd  New listing  (Minor submission) | Acute lymphoblastic leukaemia | Authority Required listing for the treatment of acute lymphoblastic leukaemia in paediatric patients when the tablet form is unsuitable. | The PBAC recommended listing mercaptopurine oral suspension as an Authority Required (Streamlined) benefit for the treatment of acute lymphoblastic leukaemia in paediatric patients in whom a solid dose form of this drug is unsuitable, on the basis of a clinical need existing for this particular dose form. |
| **MESALAZINE**  4 g granules: modified release, 30 x 4 sachets,    Pentasa®    Ferring Pharmaceuticals Pty Ltd  New listing  (Minor submission) | Inflammatory bowel disease (Crohn disease and ulcerative colitis) | Authority Required (STREAMLINED) listing of a new strength for the treatment of Crohn disease and ulcerative colitis. | The PBAC recommended the listing of mesalazine 4 g granules as an Authority Required (Streamlined) benefit for the treatment of ulcerative colitis on a cost-minimisation basis with mesalazine 2 g granules (modified release), 60 x 2 g sachets.  The PBAC noted that the submission requested mesalazine 4 g granules to be listed for both ulcerative colitis and Crohn disease indications despite the updated Product Information recommending that a daily dose of 4 g be divided for patients with Crohn disease, but not necessarily for patients with ulcerative colitis. On this basis, the PBAC recommended listing the new 4 g presentation for ulcerative colitis only. |
| **MESALAZINE**  3 g granules: modified release, 30 sachets,    Salofalk®    Aspen Australia Pty Ltd  New listing  (Minor submission) | Ulcerative colitis | Authority Required (STREAMLINED) listing of a new strength for the treatment of ulcerative colitis where hypersensitivity to sulfonamides exists or where intolerance to sulfasalazine exists. | The PBAC recommended the listing of mesalazine 3 g granules as an Authority Required (Streamlined) benefit for the treatment of ulcerative colitis where hypersensitivity to sulphonamides exists or where intolerance to sulfasalazine exists, on a cost-minimisation basis with the 1.5 g granules of Salofalk.  The PBAC considered that patients requiring a mesalazine once daily dose of 3 g would be likely to be those already prescribed the 1.5 g sachets and therefore, if the new 3 g sachets (30 sachets) were equivalently priced to the 1.5 g sachets (60 sachets), there would be minimal net financial implications of listing the new 3 g sachets. |
| **OCULAR LUBRICANTS**  Various products  Various sponsors  (Review) | Ocular lubricants | To consider the findings of the DUSC utilisation analysis of ocular lubricants and consider if the current pricing of ocular lubricants is appropriate. | The PBAC recommended that all ocular lubricants should be considered equivalent for pricing purposes. The PBAC noted that this recommendation includes ocular lubricants that contain a preservative, those that are preservative free, multi-dose products and single dose unit products.  The PBAC considered that no evidence was presented to conclude any difference in patient outcomes between the various ocular lubricants.  The PBAC noted that any submission to the PBAC requesting a price advantage should provide evidence to support any claimed superior patient outcome. |
| **OFATUMUMAB**  100 mg/5 mL injection, 5 mL vial  1 g/50 mL injection, 50 mL vial  Arzerra®  GlaxoSmithKline Australia Pty Ltd  New Listing  (Major submission) | Chronic lymphocytic leukaemia | Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with chronic lymphocytic leukaemia who meet certain criteria. | The PBAC recommended the listing of ofatumumab for the treatment of chronic lymphocytic leukaemia (CLL), on the basis of a cost-minimisation with rituximab.  Based on an indirect comparison using chlorambucil as the common comparator, ofatumumab + chlorambucil is unlikely to be superior to rituximab + chlorambucil in the treatment of previously untreated patients with CLL. The PBAC considered both ofatumumab and rituximab significantly prolong PFS when combined with chlorambucil in first line treatment of CLL, and both have an acceptable toxicity profile when combined with chlorambucil in patients unsuitable for fludarabine-based therapy. In the absence of direct trial data between ofatumumab and rituximab and given the high clinical need in the patient group, the PBAC accepted this evidence as adequate to support non-inferiority to rituximab.  The Committee agreed that dose equivalence of ofatumumab to rituximab is to be defined based on per course of treatment and calculated based on the surface area of an average patient. From the Product Information, rituximab is administered intravenously at a dose of 375 mg/m2 of body surface area on day 1 of cycle 1 and 500 mg /m2 on day 1 of cycles 2-6. |
| **OMALIZUMAB**  75 mg/0.5 mL injection, 1 x 0.5 mL syringe; 150 mg/mL injection, 1 x 1 mL syringe; 150 mg injection [1 x 150 mg vial] (&) inert substance diluent [1 x 1.2 mL ampoule], 1 pack  Xolair®  Novartis Pharmaceuticals Australia Pty Ltd  (Minor submission) | Severe allergic asthma | To propose revision of PBS restrictions and implementation requirements for omalizumab for the treatment of severe allergic asthma. | The PBAC recommended amending the restriction wording of omalizumab to align the definition of optimal asthma therapy, with regards to treatment with oral corticosteroids, with current clinical guidelines and to extend the period for assessment of response from 2 weeks to 4 weeks, as requested.  The PBAC noted that the remaining requested changes to the restriction for omalizumab would require formal evaluation of a major submission prior to consideration by PBAC. |
| **PEGINTERFERON BETA-1A**  63 microgram/0.5 mL injection, 0.5 mL syringe + 94 microgram/0.5 mL injection, 0.5 mL syringe  63 microgram/0.5 mL injection, 0.5 mL injection device + 94 microgram/0.5 mL injection, 0.5 mL injection device  125 microgram/0.5 mL injection, 2 x 0.5 mL syringes  125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices    Plegridy®    Biogen Idec Australia Pty Ltd  New Listing  (Major submission) | Multiple sclerosis | Authority Required (STREAMLINED) listing for the treatment of multiple sclerosis in patients who meet certain criteria. | The PBAC recommended the listing of peginterferon beta-1a as an Authority Required listing on a cost-minimisation basis compared with interferon beta-1a. The PBAC noted that the listing of peginterferon beta-1a would offer an alternative first line treatment for patients with remitting, relapsing multiple sclerosis.  The PBAC agreed that the equi-effective doses from the trials were peginterferon beta-1a 125 µg fortnightly to interferon beta-1a IM 30 µg once a week or interferon beta-1a SC 44 µg three times per week. |
| **PERTUZUMAB**  420 mg/14 mL injection, 1 x 14 mL vial;  Perjeta®  Roche Products Pty Ltd.  New listing  (Major submission) | HER2+metastatic breast cancer | Section 100 listing for pertuzumab in combination with trastuzumab and docetaxel for treatment of a patient with HER2+ metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for their metastatic disease and have a performance status of 0 – 1. | The PBAC recommended the listing of pertuzumab under Section 100 (Efficient Funding of Chemotherapy Drugs Program) for the treatment of HER2 positive metastatic breast cancer in combination with trastuzumab and a taxane in the first-line setting with one course of pertuzumab to be subsidised per patient lifetime. The PBAC noted substantial clinical benefit of pertuzumab in combination with trastuzumab and docetaxel compared to trastuzumab and docetaxel alone in the CLEOPATRA trial, noting a 16-month gain in median overall survival and a 6-month gain in median progression free survival.  The PBAC noted the stakeholder meeting following the deferral of pertuzumab and TDM-1. The meeting clarified the clinician and patient view on current and future treatment of mBC in Australia.  The PBAC noted that its recommended restrictions for both pertuzumab and trastuzumab are complex, with one course of pertuzumab to be subsidised per patient lifetime. It was noted that the restrictions should reflect current evidence and legitimise clinical practice by allowing use of trastuzumab beyond progression and a range of partner chemotherapy options, with the exception of nab-paclitaxel. The PBAC noted that the restrictions should ensure that patients currently accessing trastuzumab on the Herceptin program would continue to have access trastuzumab through the PBS. The finalised restrictions for trastuzumab and pertuzumab would also have flow-on consequences for the lapatinib restriction. |
| **POMALIDOMIDE**  capsules, 3 mg and 4 mg;    Pomalyst®    Celgene Pty Ltd  New listing  (Minor submission) | Myeloma | To propose a re-specified base case and revised inputs to the economic model following the July 2014 PBAC consideration for the treatment in combination with dexamethasone, of patients with relapsed and/or refractory multiple myeloma who have received and failed prior treatment with both lenalidomide and bortezomib. | The PBAC recommended the listing of pomalidomide for the treatment of multiple myeloma under the Section 100 Highly Specialised Drugs Program (HSDP).  The PBAC reiterated its view from July 2014 that there may be a clinical place for the drug in patients who have failed bortezomib and lenalidomide.  The PBAC considered that pomalidomide was not acceptably cost-effective at the price proposed. The PBAC concluded that pomalidomide would be cost-effective at a reduced price that produces an ICER, derived from the base case, that is lower than what was presented in the resubmission. |
| **RANIBIZUMAB**  2.3 mg/0.23 mL, 1 x 0.23 mL vial,  1.65 mg/0.165 mL, pre-filled syringe,  Lucentis®  Novartis Pharmaceuticals Australia Pty Ltd  Change to listing  (Minor submission) | Neovascular age-related macular degeneration | To request ranibizumab pre-filled syringe and vial presentations be “a” flagged. | The PBAC advised that ranibizumab 2.3 mg/0.23 mL solution for injection and ranibizumab 1.65 mg/0.165 mL pre-filled syringe for injection could be considered equivalent for the purposes of substitution at the point of dispensing. |
| **RITUXIMAB**  1,400 mg/11.7 mL injection,  Mabthera® SC  Roche Products Pty Ltd  New listing  (Minor submission) | Non-Hodgkin’s lymphoma | Authority Required listing of a new subcutaneously administered formulation of rituximab for patients with non-Hodgkin’s lymphoma. | The PBAC recommended an Authority Required (STREAMLINED) listing of rituximab subcutaneous injection formulation for the treatment of non-Hodgkin’s lymphoma, on the basis of non-inferior effectiveness and safety compared with rituximab intravenous infusion formulation. |
| **SALBUTAMOL**  200 microgram inhalation: powder for, 128 capsules,  Ventolin® Rotacaps®,  GlaxoSmithKline Australia Pty Ltd  Change to listing  (Out-of-session) | Asthma | Amend maximum quantity and number of repeats to align with a new pack size. | The PBAC recommended out-of-session an unrestricted benefit listing for Ventolin Rotacaps 200 microgram, 128 capsules, on a cost-minimisation basis with the currently listed pack of 100 capsules. The PBAC recommended that the maximum quantity of 200 units (2 packs) be amended to 256 units (2 packs), and, the number of repeats be amended from 5 repeats to 4 repeats. |
| **SORAFENIB** tablet, 200 mg,Nexavar®Bayer Australia Ltd Change to listing  (Minor submission) | Renal cell carcinoma | Extend the current Authority Required listing to include the treatment of stage IV clear cell variant renal cell carcinoma (advanced RCC) in patients who have failed first line treatment. | The PBAC recommended extending sorafenib’s existing listing to include second-line treatment of stage IV clear cell variant renal cell on a cost-minimisation basis against everolimus. The equi-effective doses are sorafenib 800 mg and everolimus 10 mg. The PBAC acknowledged the sentiment of a clinical need existing for further RCC treatment options to be made available to Australian patients conveyed through the consumer comments input process but cautioned against any expectations that existing drug therapies would provide a cure for RCC. |
| **SUCROFERRIC OXYHYDROXIDE** Iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90;Velphoro®Vifor Pharma Pty Ltd. New listing  (Major submission) | Hyperphosphataemia | General schedule listing (maintenance therapy) and Section 100 Authority Required (initiation of therapy) listing for the management of hyperphosphataemia in patients with chronic kidney disease who meet certain criteria. | The PBAC recommended the listing of sucroferric oxyhydroxide under Section 100 and Section 85 for the treatment of hyperphosphataemia in patients with chronic kidney disease undergoing dialysis. The recommendation was made on a cost minimisation basis with sevelamer. The equi-effective doses of sucroferric oxyhydroxide to sevelamer are estimated to be 1.8:7 (grams of iron per day), based on the maintenance doses from weeks 12-24 across the PA-CL-05A/PA-CL-05B trial phases. |
| **TRAMETINIB** 500 microgram tablet, 302 mg tablet, 30Mekinist®GlaxoSmithKline Australia Pty LtdNew listing(Major submission) | Melanoma | To provide further information to support a request for a managed entry scheme to allow the listing of trametinib as an Authority Required listing for the treatment of patients with melanoma who meet certain criteria. | The PBAC recommended an Authority required listing of trametinib, for use in combination with dabrafenib, for the treatment of advanced malignant melanoma on the basis of acceptable cost-effectiveness over dabrafenib alone, to be achieved in the context of a managed entry framework.  In making its recommendation, the PBAC considered that data from the clinical trials presented is reassuring, however the extent of benefit modelled from the BRF113220 trial appears overestimated compared with the results to date from the larger COMBI-V and COMBI-D trials. The sponsor has provided reassurances that more robust evidence will be forthcoming in the foreseeable future to better inform this modelling, and the PBAC has proposed a plan to review this evidence within two years, to make sure patients receiving medicines on the PBS are being treated according to the best available evidence and that the cost of the combination therapy remains justified in terms of acceptable cost-effectiveness. Should the modelled extent of benefits not be realised, the Committee has recommended measures to minimise risk of unjustified health care expenditure.  The PBAC considered that any MES for trametinib should be guided by the following conditions.   * The initial price for the MES would be as requested in the submission. This is despite unresolved concerns that the ICER still favours trametinib. Instead of recommending trametinib at a price justified by the existing evidence (which would be lower), a rebate with interest would be put in place, thereby ensuring that the conditions of the MES framework are fulfilled. On submission of modelling based on more conclusive evidence of cost-effectiveness from COMBI-D and COMBI-V, there would be no option for an increase in the price of trametinib, as the higher price is being paid at entry into the PBS. * The possible outcomes following the MES would be that either: * the price of trametinib (or dabrafenib) would reduce; or * the price of trametinib would be maintained. * The arrangement proposed places the financial burden on the Commonwealth for the upfront risk associated with the uncertain clinical benefit of trametinib. Accordingly, should the extent of benefit of trametinib modelled from trial BRF113220 fail to be realised in the final COMBI-D and COMBI-V results, then the sponsor would rebate the Commonwealth taking account of the following: * the price reduction of trametinib would be calculated to maintain the current ICER with reduced clinical benefits * the rebate would be calculated by multiplying this price reduction by the number of PBS-dispensed prescriptions of the combination between the date of listing and the date of implementation of the price reduction (relating to either dabrafenib or trametinib), after applying * an interest rate deemed appropriate by the Commonwealth. The repayment would apply to dabrafenib + trametinib. |
| **TRASTUZUMAB**  150 mg injection, 1 × 150 mg vial, 60 mg injection, 1 × 60 mg vial;  Herceptin®,  Roche Products Pty Ltd.  Change to listing  (Major submission) | HER2+ metastatic breast cancer | Section 100 listing for trastuzumab for treatment of a patient with HER2+ metastatic breast cancer (MBC) who has not received prior anti-HER2 therapy or chemotherapy for metastatic disease.  Section 100 listing for trastuzumab for treatment of a patient with HER2+ metastatic breast cancer whose disease has progressed despite prior treatment with trastuzumab for metastatic disease. | The PBAC recommended extending the listing of trastuzumab under Section 100 (Efficient Funding of Chemotherapy Program) for the treatment of HER2 positive metastatic breast cancer in the first-line setting as well as in patients whose disease has progressed despite treatment with trastuzumab for metastatic disease.  The PBAC recommended that implementation of this recommendation should be implemented alongside the cessation of the Herceptin program. Listing of trastuzumab on the PBS supports evidence based clinical practice, ensuring patient equity and improving cost effectiveness of trastuzumab, noting that it is a necessary partner for pertuzumab in an even more effective combination.  The PBAC reaffirmed its previous comments on the Herceptin program – specifically that for 14 years this program has provided an effective drug to patients with HER2 positive metastatic breast cancer at very high ICERs (approximately $100,000/QALY for first-line use and close to $300,000/QALY for later-line use). The PBAC noted that the cost to government was greatly in excess of predicted costs for the Herceptin program. The Herceptin program has in some instances served as a barrier to adoption of best practice evidence-based prescribing. For example the Herceptin program does not support the use of trastuzumab with non-taxane chemotherapy partners (eg vinorelbine, capecitabine).  The PBAC noted that its recommended restrictions for both pertuzumab and trastuzumab are complex, with one course of pertuzumab to be subsidised per patient lifetime. It was noted that the restrictions should reflect current evidence and legitimise clinical practice by allowing use of trastuzumab beyond progression and a range of partner chemotherapy options, with the exception of nab-paclitaxel. The PBAC noted that the restrictions should ensure that patients currently accessing trastuzumab on the Herceptin program would continue to have access trastuzumab through the PBS. The finalised restrictions for trastuzumab and pertuzumab would also have flow-on consequences for the lapatinib restriction. |
| **ZOSTER VIRUS VACCINE LIVE**  0.65 mL injection, prefilled syringe  Zostavax®  bioCSL (Australia) Pty Ltd  New listing  (Major submission) | Immunisation against herpes zoster (shingles) | National Immunisation Program (NIP) listing for an ongoing cohort of 70 year old individuals and a catch-up cohort for individuals aged 71-79 years. | The PBAC recommended the listing of zoster virus vaccine live on the National Immunisation Program (NIP) for the vaccination of immunocompetent persons aged 70 years, and a catch-up cohort of immunocompetent persons aged 71 to 79 years, at a lower price than proposed in the submission.  The PBAC considered that a claim of superior comparative effectiveness of zoster virus vaccine to placebo was reasonable, noting that the vaccine was not as effective in the 70-79 year age group compared to the 60-69 year age group for reducing incidence of zoster. However, the vaccine appears to be more effective in the reduction of post herpetic neuralgia (PHN) in the 70-79 year age group.  Assuming vaccine efficacy is maintained for 10 years (the duration suggested in the evaluation based on the approximate duration of the SPS, STPS and LTPS trials combined), the evidence presented in the re-submission suggests that for every 1000 people (ITT) receiving zoster vaccination, compared with those who are unvaccinated:   * Between 38 and 57 more people would avoid a case of zoster; and * Between 6 and 11 more people would avoid a case of PHN.   The PBAC considered that the most uncertain input into the economic model was the duration of vaccine efficacy. Overall, the PBAC considered that the estimate of duration of vaccine efficacy in the 70+year old cohort for both prevention of zoster and prevention of PHN should be 7 years to inform the respecified base case. The PBAC noted that this estimate of the duration of vaccine efficacy was lower than the estimates in the re-submission and the range of 10-13 years considered during decision making for the 60 year old ongoing cohort and the catch-up cohort for individuals aged 61-79 years in the previous submission.  Given the uncertainty of the duration of the efficacy of this vaccine against zoster and PHN and the proposed large outlay by Government, the PBAC agreed with the Australian Technical Advisory Group on Immunisation (ATAGI) that the establishment of an adult vaccination register is high priority. |