JULY 2016 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ADRENALINE I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector Adrenaline Auto Inject Sun-JV® Ranbaxy Australia (Sun Pharma) New listing (Minor Submission)	Anaphylaxis	Authority Required listing for anaphylaxis.	The PBAC recommended the listing of adrenaline 150 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection and 300 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection (Adrenaline Auto Inject Sun-JV®) as a Section 85 Authority Required listing for patients at significant risk of anaphylaxis. The PBAC noted that adrenaline auto injector products have different administration techniques and should not be prescribed or dispensed to a patient without adequate training in their use.
ALENDRONATE 70 mg tablet: effervescent, 4 Binosto® My Health 365 Pty Ltd New listing (Minor Submission)	Osteoporosis	Restricted Benefit listing for a new formulation of alendronate for the treatment of osteoporosis.	The PBAC recommended the Restricted Benefit listing of alendronic acid in the form of 70 mg effervescent tablets for the treatment of osteoporosis, on the basis that it is bioequivalent to alendronate tablets. The PBAC recommended the restriction and pricing for alendronate effervescent tablets be aligned with alendronate tablets as the two forms are bioequivalent, and because clinical superiority of the effervescent formulation over the tablet was not substantiated.
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERAL AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE 34 g bottle, powder for oral liquid, 30 TYR Easy Shake & Go® Orpharma Pty Ltd	Tyrosinaemia	Restricted Benefit listing for tyrosinaemia.	The PBAC recommended the listing of TYR Easy Shake & Go as a Restricted Benefit for tyrosinaemia on a cost-minimisation basis against TYR Express 15® at an equivalent price per gram of protein.

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New listing (Minor Submission)			
APOMORPHINE 50 mg/10 mL solution for subcutaneous infusion, 5 x 10 mL syringe MOVAPO® PFS STADA Pharmaceuticals Australia Pty Limited New listing (Minor Submission)	Parkinson disease	Section 100 (Highly Specialised Drugs Program) listing of a new formulation of apomorphine for the treatment of Parkinson disease.	The PBAC recommended the Authority Required (STREAMLINED), Section 100 (Highly Specialised Drugs Program) PBS listing of apomorphine 50 mg/10 mL, injection, pre filled syringe (MOVAPO® PFS) for the treatment of motor fluctuations associated with Parkinson disease, under the same listing conditions as the existing PBS-listed MOVAPO® injection 50 mg/5 mL and at the same price per mg.
AURANOFIN Tablet, 3 mg, 100 Riadura® Amdipharm Mercury Pty. Ltd. Change to listing (Minor Submission)	Rheumatoid arthritis	The submission requested the listing under the same conditions as the current listing for auranofin 3 mg, with an increase in maximum quantity to 100.	The PBAC recommended the addition of a maximum quantity of 100 to the current auranofin 3 mg listing, at the same price per tablet (approved ex-manufacturer price), and under the same listing conditions, as auranofin 3 mg, 60 tablet pack.

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BLINATUMOMAB Injection 38.5 microgram [1 vial] (&) inert substance solution [10 mL vial], 1 pack Blincyto® Amgen Australia Pty Ltd New listing (Major Submission)	Acute lymphocytic leukaemia	Resubmission for an Authority Required listing for acute lymphoblastic leukaemia.	The PBAC recommended an Authority Required listing of blinatumomab for the treatment of relapsed or refractory Philadelphia chromosome negative B-precursor acute lymphocytic leukaemia on the basis of acceptable cost-effectiveness over standard care chemotherapies, to be achieved in the context of a managed entry framework. In making its recommendation, the PBAC considered that blinatumomab does improve survival, however the evidence for this is comparatively weak at this point in time. There is currently a clinical trial, the TOWER Trial, being conducted of blinatumomab. The preliminary results from this trial provide reassurance that more robust evidence will be forthcoming in the foreseeable future. The PBAC has proposed to review this evidence as soon as it becomes available to ensure patients receiving medicines on the PBS are being treated according to the best available evidence and that the cost of the treatment remains justified. This places the financial burden on the Commonwealth for the upfront risk associated with the uncertain clinical benefit of blinatumomab. The PBAC considered that this risk should be dealt with through a managed entry scheme (MES), guided by the following conditions: • The initial price for blinatumomab in the MES would be established based on respecifying of the base case of the submitted model to use only the weighted historical control data from patients diagnosed post-2000 for the comparator; • The possible outcomes following completion of the MES would be that either: o the price of blinatumomab would reduce; or o the price of blinatumomab would be

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			maintained. • Any price reduction of blinatumomab would be calculated to maintain the current incremental cost effectiveness ratio (ICER) with reduced clinical benefits; and • A rebate for payments made while the drug was subsidised at a higher price would be calculated by multiplying the price reduction by the number of PBS-dispensed prescriptions of blinatumomab between the date of listing and the date of implementation of the price reduction (after applying an interest rate deemed appropriate by the Commonwealth).
BUPRENORPHINE 5 µg/hour patch 10 µg/hour patch 15 µg/hour patch 20 µg/hour patch 25 µg/hour patch 30 µg/hour patch 40 µg/hour patch Norspan® Mundipharma Pty Ltd Change to listing (Minor Submission)	Chronic severe disabling pain	Authority Required (STREAMLINED) listing on the palliative care schedule providing up to 3 months' supply.	The PBAC recommended listing all currently available strengths of buprenorphine transdermal patches on the Palliative Care Schedule as an Authority Required listing with a maximum quantity of 4 patches with two repeats, providing up to three months' supply in each prescription. The PBAC recommended that the listing for buprenorphine be aligned with the listing for modified release morphine on the Palliative Care Schedule.

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DASATINIB 20 mg tablet, 60 50 mg tablet, 60 70 mg tablet, 60 100 mg tablet, 30 Sprycel® Bristol-Myers Squibb Australia Ltd Change to listing (Minor Submission)	Chronic myeloid leukaemia	Resubmission to request an amendment to the current first-line PBS restriction for dasatinib for treatment of patients with chronic myeloid leukaemia to ensure consistency with the first-line listing for the alternative tyrosine kinase inhibitor, imatinib.	The PBAC recommended amending the current PBS listings for dasatinib for use in first-line treatment of chronic myeloid leukaemia by changing the benefit type from Authority Required (Written) to Authority Required (Telephone) for second continuing and subsequent treatment applications.
DENOSUMAB 60 mg/mL injection, 1 x 1 mL syringe Prolia® Amgen Australia Pty Ltd Change to listing (Minor Submission)	Osteoporosis	Request to change the current listing for the treatment of osteoporosis to allow prescribing by Nurse Practitioners for initiation of therapy.	The PBAC recommended a change to the PBS listing for denosumab to allow initiation of treatment of osteoporosis by nurse practitioners, aligning with the prescriber types approved for the PBS prescribing of other treatments for osteoporosis including bisphosphonates and raloxifene.

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DENOSUMAB 120 mg/1.7 mL injection, 1 x 1.7 mL vial Xgeva® Amgen Australia Pty Ltd Change to listing (Minor Submission)	Hypercalcaemia of malignancy	Resubmission for an Authority Required (STREAMLINED) listing for the treatment of hypercalcaemia of malignancy which is refractory to intravenous biphosphonate therapy.	The PBAC recommended the Authority Required (STREAMLINED) listing of denosumab for the treatment of hypercalcaemia of malignancy, on a cost minimisation basis to pamidronate. The equi-effective dose was considered to be 5 subcutaneous injections of 120 mg denosumab to one 90 mg infusion of pamidronate. The PBAC considered that the clinical place for denosumab was in malignancy refractory to anti-neoplastic therapy and refractory to bisphosphonates. Data were not provided to show that denosumab was superior to pamidronate nor non-inferior to zoledronic acid.
DIMETHYL FUMARATE 120 mg capsules Tecfidera® Biogen Australia Pty Ltd Change to listing (Minor Submission)	Relapsing-remitting multiple sclerosis	Request amendment to the PBS maximum quantity of dimethyl fumarate 120 mg to allow flexibility in dose titration.	The PBAC recommended increasing the maximum quantity of 120 mg dimethyl fumarate tablets from one to two packs for both the initial and continuing dose titration periods. In making its recommendation, the PBAC considered that increasing the maximum quantity would simplify dose titration for patients and medical practitioners.

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dTpa VACCINE 0.5 mL injection Boostrix® GlaxoSmithKline Australia Pty Ltd Change to listing (Major Submission)	Prevention of pertussis	National Immunisation Program listing for maternal vaccination against pertussis (via vaccination of pregnant women, during third trimester of pregnancy).	The PBAC recommended a change to the circumstances under which combined diphtheria, tetanus and acellular pertussis (dTpa) vaccine is made available as a designated vaccine for the National Immunisation Program (NIP) to include vaccination of women during each pregnancy to reduce pertussis disease in infants (prior to being vaccinated) and in mothers on the basis of cost-effectiveness compared with no vaccination. The PBAC noted that the states and territories currently fund dTpa vaccination during pregnancy in line with the Australian Immunisation Handbook recommendation (section 4.12.7). The PBAC considered that the introduction of dTpa for pregnant women on the NIP is warranted from a public health perspective as an additional measure to directly target the group with the highest burden of disease (i.e. infants). The PBAC considered that vaccination of women during each pregnancy is likely to reduce pertussis disease in infants and mothers. The PBAC noted that, based on the non-randomised observational data, maternal vaccination is estimated to reduce the number of cases of pertussis in infants aged less than three months by 91%. The PBAC considered that vaccination with dTpa is inferior in safety compared with no vaccination, particularly with regards to local injection site reactions. However, the PBAC accepted that the safety profile was acceptable, noting that dTpa vaccination during pregnancy has not been associated with an increased risk of maternal or infant events, such as still birth, maternal or neonatal death, preterm delivery, pre-eclampsia, post-partum haemorrhage or low birth weight. The PBAC considered that some assumptions included in the economic model presented in the submission were likely to have overestimated the cost-effectiveness of maternal

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			dTpa vaccination whereas others may have underestimated the cost-effectiveness. However, on balance and in the context of the public health imperative to prevent severe infection in infancy, the PBAC accepted that the incremental cost effectiveness ratio was likely to be around $15,000 to $45,000 per Quality Adjusted Life Year (QALY) gained. The PBAC considered that it would be preferable to examine the pertussis vaccination schedule as a whole rather than limit the assessment to cost-effectiveness of each individual vaccination. In this regard, the PBAC noted that one of the primary aims of pertussis containing vaccines on the NIP is to prevent disease in vulnerable infants. Given that maternal vaccination provides direct protection to infants in the first few months of life, the PBAC considered that dTpa vaccination of pregnant women was likely to be reasonably cost-effective. However, the PBAC requested advice from ATAGI on the clinical place and effectiveness of the vaccines currently listed on the NIP schedule aimed at preventing pertussis disease, particularly in light of the inclusion of dTpa vaccination of pregnant women and recent inclusion of an 18 month vaccine dose, with a view to potentially informing a review of the cost effectiveness of these vaccines.

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ETANERCEPT 50 mg/mL injection, 1 mL pre-filled syringe, 4 50 mg/mL injection, 1 mL auto-injector, 4 Brenzys® Merck Sharp and Dohme (Australia) Pty Limited New listing (Major Submission)	Rheumatoid arthritis; Psoriatic arthritis; Plaque psoriasis; Ankylosing spondylitis;	To request listing of Brenzys® (etanercept), a similar biological medicinal product, with the same indications and restrictions as the currently PBS listed brand of etanercept (Enbrel), including the Authority Required listing for rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, and ankylosing spondylitis.	The PBAC recommended the listing of Brenzys® as a biosimilar of originator brand etanercept (Enbrel®) on a cost minimisation basis with Enbrel for all adult indications – rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and chronic plaque psoriasis. The PBAC considered that the evidence presented in the submission supported the claims of comparative safety and effectiveness of Brenzys and Enbrel. The PBAC advised the Minister that it considered the Enbrel and Brenzys brands of etanercept could be marked as equivalent in the Schedule of Pharmaceutical Benefits ('a' flagged), for the purposes of substitution by the pharmacist at the point of dispensing for all the circumstances (restrictions) that both brands are listed against. The PBAC noted that the substitution process allows for patient and prescriber choice and is not automatic. For any individual prescription, a prescriber may choose to not permit brand substitution. If substitution has been permitted by the prescriber, the patient may choose which brand they wish to receive from the pharmacist. In forming its view on brand substitution ('a' flagging), the PBAC considered a range of factors including: • The evidence presented in the SB4-G31-RA trial in treatment-naïve patients initiating on either Enbrel or Brenzys supported a finding that Brenzys has equivalent effectiveness and equivalent safety compared to Enbrel. • The key randomised clinical study in rheumatoid arthritis did not indicate differences in efficacy or safety of Brenzys compared with Enbrel. • The clinical data provided in the submission did not suggest there were any identified populations where the risks of using the biosimilar product in place of

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			the reference biologic were disproportionately high. • In the SB4-G31-RA Phase III extension study, which included 52 weeks of additional data, including from a one-way switch from Enbrel to Brenzys, the clinical evidence suggested no difference in efficacy, safety or immunogenicity between the biosimilar and the reference biologic. • The drug, etanercept, is not immunogenic per se, and anti-drug antibodies are rare. Switching between brands of etanercept is unlikely to change this. • The Advisory Committee on Prescription Medicines (ACPM) has declared Brenzys a biosimilar for Enbrel. The ACPM was satisfied of the similar safety and efficacy of Brenzys and Enbrel in rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis and non-radiographic axial spondyloarthritis.
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS oral liquid: powder for, 30 x 51 g sachets PKU Bettermilk Lite® Cortex Health Pty Ltd New listing (Minor Submission)	Phenylketonuria	Restricted Benefit listing for phenylketonuria.	The PBAC recommended the listing of PKU Bettermilk Lite as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against Camino Pro Bettermilk® at an equivalent price per gram of protein.

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GRAZOPREVIR with ELBASVIR grazoprevir 100 mg + elbasvir 50 mg tablet, 28 Zepatier® Merck Sharp and Dohme (Australia) Pty Limited New listing (Major Submission)	Chronic Hepatitis C virus infection	Authority Required (STREAMLINED) listing for treatment of Chronic Hepatitis C infection.	The PBAC recommended the Authority Required listing of grazoprevir with elbasvir (GRZ/EBR) for the treatment of chronic hepatitis C virus (CHC) infection for treatment-naïve and treatment experienced genotypes (GT) 1, 4 and 6 patients. The PBAC did not recommend listing GRZ/EBR for treatment naïve GT 3 CHC. Evidence from two phase III and three phase II randomised clinical trials were presented in the submission, and the PBAC was satisfied that sufficient evidence was available to recommend regimens containing GRZ/EBR. The PBAC considered the evidence for GT 1 was sufficient to establish safety and effectiveness. For GT 4 and 6, the PBAC agreed there was a clinical need for treatment regimens that do not contain peg-interferon and recommended GRZ/EBR for these genotypes. The PBAC considered that there were insufficient data to recommend GRZ/EBR for listing for GT 3.
IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig® Gilead Sciences Pty Ltd Matters Outstanding (Minor Submission)	Chronic lymphocytic leukaemia and small lymphocytic lymphoma	Resubmission for Authority Required listing for the treatment of relapsed or refractory chronic lymphocytic leukaemia or small lymphocytic leukaemia.	The PBAC recommended the listing of idelalisib in combination with rituximab for use in patients with relapsed/refractory chronic lymphocytic leukaemia or small lymphocytic lymphoma. The PBAC acknowledged that idelalisib, in combination with rituximab, provides a progression free survival and overall survival advantage when compared to best supportive care with rituximab. The risk of significant adverse events with idelalisib use remained an issue of significant concern for PBAC.

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IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig® Gilead Sciences Pty Ltd Matters Outstanding (Minor Submission)	Follicular Lymphoma	Resubmission for Authority Required listing for the treatment of relapsed/refractory follicular lymphoma that has progressed despite prior treatment with rituximab and an alkylating agent.	The PBAC recommended the Authority Required listing of idelalisib as monotherapy for the treatment of follicular B-cell non-Hodgkin's lymphoma that is refractory to both rituximab and an alkylating agent. The PBAC noted the high unmet clinical need for effective treatment for these patients, considering that idelalisib is a clinically effective last-line treatment option. The risk of significant adverse events with idelalisib use remained an issue of significant concern for the PBAC, and therefore recommended that the listing of idelalisib for this indication should only proceed following further safety updates from the TGA. The PBAC maintained that the ICER remained high, but considered it acceptable for this patient population for whom there are few treatment options.
IPILIMUMAB 50 mg/10 mL injection, 10 mL 200 mg/40 mL injection, 40 mL Yervoy® Bristol-Myers Squibb Australia Ltd Change to listing (Minor Submission)	Metastatic melanoma	Request to change the wording in the current restriction from 'the treatment must be as monotherapy' to 'the treatment must be the sole PBS-subsidised therapy for this condition'	The PBAC recommended the PBS restriction for ipilimumab for the treatment of unresectable stage III or stage IV malignant melanoma be amended to read 'The treatment must be the sole PBS-subsidised therapy for this condition', on the basis that it would remain as an Authority Required (STREAMLINED) listing only under special arrangements under Section 100 Efficient Funding of Chemotherapy. The PBAC was satisfied that the proposed change in restriction wording was consistent with other PBS listed agents currently available for the treatment of this condition.

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IXEKIZUMAB 80 mg/mL injection 2 x 1 mL syringe 80 mg/mL injection 2 x 1 mL injection device Taltz® Eli Lilly Australia Pty Ltd New listing (Major Submission)	Plaque psoriasis	Authority Required listing for severe chronic plaque psoriasis.	The PBAC recommended an Authority Required listing of ixekizumab for the treatment of severe chronic plaque psoriasis that is refractory to treatment with non-biological DMARDs. The PBAC accepted that the clinical place in therapy for treatment with ixekizumab would be as an alternative treatment option to the currently PBS listed bDMARDs. The PBAC noted the availability of five alternative bDMARDs listed on the PBS for the treatment of severe chronic plaque psoriasis and concluded that it was uncertain how ixekizumab addressed a clinical need that was not provided by another bDMARD. The PBAC noted that in the sponsor's pre-PBAC response, the nominated comparator was changed (from ustekinumab in the submission) to secukinumab. The PBAC considered that any of the currently PBS listed bDMARDs could be an appropriate alternative therapy, and that in the absence of demonstrated superior comparative effectiveness or safety over the alternative therapies, ixekizumab should be cost-minimised to the least costly bDMARD. The PBAC did not accept the submission's claim that ixekizumab was superior in comparative effectiveness and equivalent in comparative safety over ustekinumab and adalimumab. Noting potential exchangeability issues, and that only short-term comparative outcomes were available, the PBAC considered that there was no clear evidence that ixekizumab provided a significant improvement in efficacy or reduction of toxicity compared to the alternative bDMARDs.

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LENVATINIB 4 mg capsule, 30 10 mg capsule, 30 Lenvima® Eisai Australia Matters Outstanding (Minor submission)	Thyroid cancer	The resubmission requested an Authority Required listing for lenvatinib for treatment of locally advanced or metastatic radioactive iodine refractory differentiated thyroid cancer.	The PBAC recommended the listing of lenvatinib for the treatment of radioactive iodine refractory differentiated thyroid cancer (RAI-R DTC) on the basis of acceptable cost effectiveness over best supportive care. The listing was recommended based on the new offered price and a risk sharing arrangement.
LEUPRORELIN AND BICALUTAMIDE Leuprorelin 7.5 mg injection and bicalutamide 50 mg tablet, 28 Leuprorelin 22.5 mg injection and bicalutamide 50 mg tablet, 28 Leuprorelin 22.5 mg injection and bicalutamide 50 mg tablet, 84 Bi Eligard CP® Tolmar Australia Pty Ltd New listing (Minor Submission)	Metastatic (Stage D) prostate cancer	Restricted Benefit listing of a combination pack containing leuprorelin and bicalutamide for metastatic (Stage D) prostate cancer.	The PBAC recommended the listing of the leuprorelin and bicalutamide combination pack for metastatic (Stage D) prostate cancer on a cost minimisation basis compared with the individual components. In making this recommendation, the PBAC noted that co-prescribed leuprorelin and bicalutamide has been used for many years, and an equivalent combination pack containing goserelin and bicalutamide has been on the PBS for more than five years with stable use.
MEPOLIZUMAB 100 mg/10 mL vial, powder for injection, 1	Severe eosinophilic asthma	Resubmission for a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of severe eosinophilic asthma.	The PBAC recommended the Section 100 (Highly Specialised Drugs Program) listing of mepolizumab on a cost-minimisation basis with omalizumab. The PBAC noted that the minor resubmission presented arguments for incorporating utilisation data into the calculation of equi-

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Nucala® GlaxoSmithKline Australia Pty Ltd New listing (Minor Submission)			effective doses, but maintained their previous view that the equi-effective doses should be derived from clinical trial data. The equi-effective doses accepted by PBAC were mepolizumab 100 mg and omalizumab 398 mg.
MILK POWDER - LACTOSE INTOLERANCE FORMULA Oral liquid: powder for, 900 g S-26 Original LI® Aspen Pharmacare Australia Pty Ltd New listing (Minor Submission)	Lactose intolerance in infants	Authority Required listing for the treatment of acute and chronic lactose intolerance in infants up to the age of 12 months to replace the current listings for Milk Powder Lactose Free Formula (S-26 LF).	The PBAC recommended the listing of S-26 Original LI® as a written Authority Required benefit for the treatment of acute lactose intolerance, on a cost-minimisation basis against S-26 LF® at an equivalent price. S-26 Original LI® will be a direct replacement for S-26 LF®, which will be removed from the PBS.
OMALIZUMAB 75 mg/0.5 mL injection, 1 x 0.5 mL syringe 150 mg/mL injection, 1 x 1 mL syringe Xolair® Novartis Pharmaceuticals Australia Pty Ltd Change to listing (Major Submission)	Paediatric severe allergic asthma	Authority Required listing for treatment of severe allergic asthma in patients aged 6 to less than 12 years.	The PBAC recommended a Section 100 (Highly Specialised Drugs Program) listing of omalizumab for treatment of severe allergic asthma in patients aged 6 years to less than 12 years. The recommendation was made on the basis of sufficient evidence to demonstrate the effectiveness of omalizumab when compared to placebo plus optimised asthma therapy. The benefits from using omalizumab to reduce severe asthma exacerbations was considered to be important for the small paediatric population, as there are currently limited options available to treat the proposed group and long term oral steroid use is undesirable.

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PNEUMOCOCCAL CONJUGATE VACCINE 13-Valent Adsorbed Pre-Filled Syringe, 0.5 mL Prevenar 13® Pfizer Australia Pty Ltd Change to listing (Major Submission)	Prevention of pneumococcal disease	National Immunisation Program (NIP) listing for pneumococcal naive non-Indigenous adults aged 65 years and over and Indigenous adults aged 50 years and over.	The PBAC recommended a change to the circumstances under which 13-valent Pneumococcal Conjugate Vaccine (13vPCV) is made available as a designated vaccine on the NIP for the prevention of pneumococcal pneumonia and invasive pneumococcal disease (IPD) in adults on the basis of cost-effectiveness compared with 23-valent pneumococcal polysaccharide vaccine (23vPPV, Pneumovax® 23) The PBAC recommended that a single dose of 13vPCV be made available to pneumococcal vaccine naïve non-Indigenous adults aged 65 years and over and to pneumococcal vaccine naïve Indigenous adults aged 50 years and over. The PBAC recommended that this dose of 13vPCV should replace the single dose (or the first dose for those adults with risk factors) of 23vPPV that is currently provided to these populations. The PBAC noted that if 13vPCV was included on the NIP for adults, then individuals in specified at-risk groups would continue to receive 23vPPV five years following the primary dose of 13vPCV. The PBAC recalled it previously noted that the evidence for 13vPCV over no vaccination was of higher quality than for 23vPPV over no vaccination. In the absence of direct comparative evidence between 13vPCV and 23vPPV, the PBAC accepted that the effectiveness of 13vPCV against community-acquired pneumonia (CAP) is likely to be superior to that of 23vPPV. The PBAC also accepted that the effectiveness of 13vPCV against IPD was likely to be at least equivalent to that of 23vPPV where IPD was caused by serotypes common to both vaccines, but not where IPD was caused by serotypes contained only within 23vPPV. The PBAC noted that no new evidence on the comparative effectiveness of 13vPCV and 23vPPV was presented, and therefore did not change its previous recommendation regarding the clinical claims.

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			The PBAC accepted the base case for the economic model in the pre-PBAC response which resulted in an ICER of less than $15,000 per QALY gained, and noted that the ICER varied from less than $15,000 to $15,000-$45,000 per QALY gained under a range of scenarios. The PBAC considered that the revised economic model, and the price reduction offered in the resubmission, enabled the Committee to have greater confidence that the requested listing of would be cost effective compared with 23vPPV. The PBAC noted that the cost-effectiveness of 23vPPV had not been previously reviewed. It was further noted that the information provided in the 13vPCV submission suggested that 23vPPV is unlikely to prevent community acquired pneumonia, and the impact on the incidence of IPD may be minimal because of the short duration of protection and the reduction in 13vPCV-serotypes due to the infant programme. The PBAC requested advice from ATAGI on the clinical place and effectiveness of 23vPPV on the NIP with a view to potentially informing a review of the cost-effectiveness of 23vPPV compared with no vaccine. This review should include the use of 23vPPV as currently specified in the NIP schedule (i.e. in children and Aboriginal and Torres Strait Islander adolescents medically at risk and in adults with and without risk factors).The PBAC noted that any outcomes of the review of 23vPPV may have implications for the 13vPCV listing.

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PROGESTERONE 200 mg capsule, 42 Utrogestan® Besins Healthcare New listing (Minor Submission)	Assisted reproduction	Resubmission for Section 100 (IVF Program) Authority Required (STREAMLINED) listing for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle.	The PBAC recommended the Section 100 (IVF Program) Authority Required (STREAMLINED) listing for progesterone for luteal support as part of an assisted reproductive technology (ART) treatment program for infertile women. The PBAC considered that any form of progesterone currently listed on the PBS for ART could be an appropriate comparator, and that in the absence of demonstrated superior comparative effectiveness or safety over the least costly comparator, progesterone 200 mg capsule should be cost-minimised to the least costly comparator, progesterone pessary. The PBAC considered that the equi-effective doses were progesterone (Utrogestan) 200 mg capsule administered vaginally three times daily and the previously accepted progesterone equi-effective doses, which are Oripro pessary 200-800 mg daily and Endometrin vaginal tablet 100 mg twice or three times daily. The PBAC noted that no clinical evidence was provided to demonstrate the superiority of higher progesterone doses over lower doses.
RIBAVIRIN 200 mg tablet Ibavyr® Clinect Pty Ltd New listing (Minor Submission)	Chronic hepatitis C virus infection	Authority Required Section 85 and Section 100 (Highly Specialised Drugs Program) listing of a new strength of ribavirin for the same indications as the currently listed strengths.	The PBAC recommended the listing of ribavirin 200 mg, for use in combination therapy with other oral agents for treating chronic hepatitis C infection, under the same listing conditions and at an equivalent ex-manufacturer price as existing strengths ribavirin on the PBS. The availability of 200 mg tablets removes the need for the physical splitting of higher strength tablets to achieve lower doses in modified dosing regimens. The listing of the 200 mg strength will be cost neutral to the PBS.
RIBAVIRIN	Chronic hepatitis C	Authority Required Section 85 and Section	The PBAC recommended the listing of ribavirin in

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
400 mg tablet 600 mg tablet Ibavyr® Clinect Pty Ltd Change to listing (Minor Submission)	virus infection	100 (Highly Specialised Drugs Program) listing of ribavirin, in combination with daclatasvir and sofosbuvir, for the treatment of genotypes 2, 3, 4, 5 and 6 Hepatitis C viral infection in patients 18 years or older who have decompensated liver disease.	combination with daclatasvir and sofosbuvir for 12 weeks for the treatment of genotype 3 hepatitis C virus in treatment naïve and treatment experienced cirrhotic patients. The PBAC also recommended a footnote be added to the genotype 3 daclatasvir with sofosbuvir 24 week regimen to allow for the addition of ribavirin to this regimen when clinically appropriate, for example in patients with decompensated liver disease.
RUXOLITINIB 10 mg tablet, 56 Jakavi® Novartis Pharmaceuticals Australia Pty Ltd New listing (Minor Submission)	Myelofibrosis	Authority Required listing for a new strength of ruxolitinib for the same indications as the currently listed strengths of ruxolitinib.	The PBAC recommended the listing of ruxolitinib 10 mg as a section 85 Authority Required listing, for first-line or second-line management of myelofibrosis under the same listing conditions, and with the same pricing arrangement, as for the currently PBS listed strengths.
TRAMETINIB 2 mg tablet, 90 0.5 mg tablet, 90 Mekinist® Novartis Pharmaceuticals Australia Pty Ltd Matter arising (Major Submission)	Melanoma	To seek PBAC reconsideration of the cost-effectiveness of trametinib for the treatment of metastatic melanoma and to fulfil the requirements of the Managed Entry Scheme.	The PBAC recommended continuation of the Authority required listing of trametinib, for use in combination with dabrafenib, for the treatment of patients with BRAF V600 mutation positive unresectable stage III or metastatic (stage IV) malignant melanoma. The PBAC accepted the inclusion of the PBS-relevant post-progression anti-cancer treatment (PPACT) costs in the model. The PBAC recalled that it has accepted the inclusion of these types of costs in its consideration of other medicines previously. After reviewing the finalised results of the COMBI-D and

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			COMBI-V trials, the PBAC considered that the clinical benefit of trametinib in terms of prolongation of progression-free survival and overall survival had been over-estimated when approved in November 2014. As a result, the PBAC recommended that the effective price of trametinib be reduced to maintain acceptable cost-effectiveness.