MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ALIROCUMAB Injection 75 mg in 1 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Praluent® Sanofi-Aventis Australia Pty Ltd New listing (Major Submission)	Hypercholesterolaemia	Resubmission to request an Authority Required listing for the treatment of patients: • with heterozygous familial hypercholesterolaemia (he-FH); or • with hypercholesterolaemia with previous acute coronary syndrome and concomitant diabetes.	The PBAC recommended an Authority Required listing of alirocumab for the treatment of patients with he-FH with high cardiovascular risk (patients with atherosclerotic disease and/or very high LDL levels) on a cost-minimisation basis to evolocumab. The PBAC advised that the listing of alirocumab for he-FH patients should have the same restriction wording and equivalent price as the evolocumab approval in March 2018. The PBAC did not recommend the listing of alirocumab for patients with non-familial hypercholesterolaemia (non-FH) with acute coronary syndrome and diabetes based on an inadequately defined high-risk patient population, and a high and uncertain incremental cost-effectiveness ratio. The PBAC considered the ODYSSEY OUTCOMES trial supported alirocumab as an effective agent with robust cardiovascular outcomes. However, the population required more refined eligibility criteria in the proposed PBS listing given concerns around the economic modelling and the high financial estimates.
ATEZOLIZUMAB and BEVACIZUMAB Atezolizumab: Solution concentrate for I.V. infusion 1200 mg in 20 mL Bevacizumab: Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Tecentriq® and Avastin® Roche Products Pty Ltd Change to listing (Major Submission)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of metastatic NSCLC in combination with platinum-doublet chemotherapy (PDC) in: • epidermal growth factor receptor (EGFR) wild type/ anaplastic lymphoma kinase (ALK) negative patients; or • EGFR/ALK mutation positive patients who have progressed on or after prior treatment with a tyrosine kinase inhibitor.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of atezolizumab and bevacizumab in combination with PDC, for the first line treatment of patients with stage IV metastatic non-squamous (NSQ) NSCLC. The PBAC was satisfied that atezolizumab + bevacizumab in combination with PDC provides, for some patients, a significant improvement in efficacy over PDC, or, for patients with PD-L1 TPS ≥ 50%, EGFR/ALK negative, NSQ disease, that atezolizumab with bevacizumab in combination with PDC will deliver similar clinical outcomes to pembrolizumab followed by chemotherapy.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BENZATHINE BENZYLPENICILLIN Injection 517 mg in 1.17 mL single use pre-filled syringe Bicillin L-A® Pfizer Australia Pty Ltd New listing (Minor Submission)	Treatment of infections	To request an unrestricted benefit listing of a new strength of benzathine benzylpenicillin injection.	The PBAC recommended the unrestricted General Schedule listing of a new additional strength of benzathine benzylpenicillin (0.6 million units (517 mg) in 1.17 mL pre-filled syringe, Bicillin L-A®) at an equivalent price per unit to the currently listed strength (1.2 million units (900 mg) in 2.3 mL pre-filled syringe).
BOTULINUM TOXIN TYPE A Lyophilised powder for injection 100 units Botox® Allergan Australia Pty Ltd Change to listing (Minor Submission)	Focal spasticity of the lower limb	Resubmission to request an extension to the current Section 100 (Botulinum Toxin Program) listing to include the treatment of lower limb focal spasticity in adults following stroke, who meet certain conditions.	The PBAC recommended the extension to the existing Section 100 (Botulinum Toxin Program) listing of botulinum toxin type A (Botox®) to include treatment of lower limb focal spasticity following an acute neurological event. An acute neurological event included, but was not limited to, stroke, traumatic brain injury, spinal cord injury, hypoxia or infection. In November 2018, the PBAC considered that there was a clinical need for effective treatments for lower limb focal spasticity following stroke. In the March 2019 resubmission, the PBAC noted the request to add additional acute aetiologies, including traumatic brain and spinal cord injuries, to the requested population. The PBAC noted that this request was supported by the Rehabilitation Medicine Society of Australia and New Zealand (RMSANZ). The PBAC considered that, despite the lack of clinical trials in these populations, the request was reasonable and biologically plausible. The PBAC considered the restriction as proposed by the sponsor in its pre-PBAC Response was reasonable, noting that the recommendations made in November 2018 relating to condition eligibility, initiation and stopping rule criteria and the maximum number of treatment cycles per year had been incorporated. The PBAC also noted that the resubmission addressed residual concerns about the eligible population and economic model. The Committee considered it was appropriate for patients with spasticity following acute neurological events to be able to access treatment.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BUDESONIDE Capsule (modified release) 3 mg Budenofalk® Orphan Australia Pty Ltd New listing (Minor Submission)	Crohn disease	To request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn disease.	The PBAC recommended the listing of budesonide for the treatment of mild to moderate Crohn's disease affecting the ileum and/or ascending colon. The PBAC recommended the listing on a cost-minimisation basis against a weighted mixed comparator of mesalazine and prednisolone.
BUDESONIDE Capsule (modified release) 3 mg Entocort® Emerge Health Pty Ltd New listing (Minor Submission)	Mild to moderate Crohn disease	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn disease.	The PBAC recommended the listing of budesonide for the treatment of mild to moderate Crohn's disease affecting the ileum and/or ascending colon. The PBAC recommended the listing on a cost-minimisation basis against a weighted mixed comparator of mesalazine and prednisolone.

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BUPRENORPHINE Injection 8 mg in 0.16 mL pre-filled syringe Injection 16 mg in 0.32 mL pre-filled syringe Injection 24 mg in 0.48 mL pre-filled syringe Injection 32 mg in 0.64 mL pre-filled syringe Injection 64 mg in 0.18 mL pre-filled syringe Injection 96 mg in 0.27 mL pre-filled syringe Injection 128 mg in 0.36 mL pre-filled syringe Buvidal® Camurus AB New listing (Minor Submission)	Opiate dependence	Resubmission to request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opiate dependence.	The PBAC recommended the Section 100 (Opiate Dependence Treatment Program) listing for buprenorphine prolonged release subcutaneous injection for the treatment of opiate dependence on a cost-minimisation basis with sublingual buprenorphine with naloxone. The PBAC considered that, based on available clinical evidence, prolonged release buprenorphine provided the same clinical benefits as sublingual buprenorphine with naloxone; however it acknowledged there was a clinical need for an alternative form which was likely to have both clinical and social advantages for some patients in this treatment setting. On that basis, the PBAC considered a modest price premium over the existing sublingual formulation was reasonable.
CALCIUM Tablet, chewable, 500 mg (as carbonate) Cal-500® Petrus Pharmaceuticals Pty Ltd New listing (Minor Submission)	Hyperphosphataemia	To request an Authority Required (STREAMLINED) listing of a new larger pack size of calcium for the treatment of hyperphosphataemia.	The PBAC recommended the listing of a 120 tablet pack size of Cal-500 which is intended to replace the currently listed 60 tablet pack size.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
CERTOLIZUMAB PEGOL Injection 200mg in 1 mL pre-syringe pen Solution for injection 200 mg in 1 mL pre-filled pen Cimzia® UCB Australia Pty Ltd Change to listing (Major Submission)	Severe chronic plaque psoriasis	To request an Authority Required listing for the treatment of patients with severe chronic plaque psoriasis.	The PBAC recommended the Authority Required listing of certolizumab pegol on a cost-minimisation basis with the least costly alternative biological disease modifying anti-rheumatic drug (bDMARD) for the treatment of severe chronic plaque psoriasis.
CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units Dysport® Ipsen Pty Ltd Change to listing (Minor Submission)	Spasticity of the upper limb	Resubmission to extend the current Section 100 (Botulinum Toxin Program) listing to include treatment of patients with moderate to severe spasticity of the upper limb following an acute event, and to remove the current restriction on the number of treatment periods in a lifetime.	The PBAC recommended an extension of the current Section 100 (Botulinum Toxin Program), Authority Required (STREAMLINED) listing for clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) for treatment of moderate to severe focal spasticity of the upper limb following a stroke, to also include spasticity following acute events other than stroke. The PBAC acknowledged the clinical need for effective treatment options in this patient population and was satisfied that Dysport® provides, for some patients, a modest improvement in efficacy compared with standard of care. The PBAC noted that although no new clinical data was presented in the resubmission, the proposed Risk Sharing Arrangement helped mitigate the outstanding uncertainty surrounding the clinical benefit, the cost-effectiveness and the financial implication of Dysport in the extended population.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DASATINIB Tablet 20mg Tablet 50mg Tablet 70mg Tablet 100mg Sprycel® Bristol-Myers Squibb Australia Pty Ltd Change to listing (Minor Submission)	Acute lymphoblastic leukaemia (ALL)	To request an extension to the current Authority Required listing for the treatment of Philadelphia chromosome positive (Ph+) ALL to include newly diagnosed patients.	The PBAC recommended the listing of dasatinib for the treatment of patients with newly diagnosed Ph+ ALL. The PBAC's recommendation for listing was based on its assessment that the cost-effectiveness of dasatinib would be acceptable if it were cost-minimised against imatinib. The PBAC considered the claim that dasatinib in combination with chemotherapy or corticosteroids is comparable in both efficacy and safety to imatinib in combination with chemotherapy or corticosteroids for the first-line treatment of patients with Ph+ ALL to be reasonable although based on limited clinical evidence. The PBAC considered dasatinib may be a better treatment option for some patients given its penetration into the central nervous system.
ENOXAPARIN Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe Clexane® Sanofi-Aventis Australia Pty Ltd Change to listing (Minor Submission)	Venous thromboembolism (VTE) prophylaxis	To request an increase in the maximum number of repeats from 0 to 1 for the unrestricted listing of enoxaparin.	The PBAC recommended a change to the PBS listing for enoxaparin 20mg/0.2 mL and 40 mg/0.4 mL to increase the maximum number of repeats from zero to one. The increase in repeats will provide appropriate supply for patients requiring VTE prophylaxis beyond 20 days.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
FLUTICASONE FUROATE with UMECLIDINIUM and VILANTEROL Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses Trelegy® Ellipta® GlaxoSmithKline Australia Pty Ltd Change to listing (Major Submission)	Chronic Obstructive Pulmonary Disease (COPD)	To request a change to the current clinical criteria to remove the requirement for patients to have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy.	The PBAC recommended an extension to the existing Authority Required (STREAMLINED) listing of fluticasone furoate with umeclidinium and vilanterol (Trelegy) for COPD, specifically the removal of the FEV1 threshold from the clinical criteria in the restriction. The PBAC recommended the extension of the existing listing on the basis that triple therapy is cost-effective over dual therapy (long acting muscarinic receptor antagonist (LAMA)/long acting beta-2 adrenoreceptor agonist (LABA)) in this population. The PBAC considered that the requested removal of the clinical criteria (FEV1<50% predicted) was also applicable to all inhaled corticosteroid /LABA fixed dose combination products for COPD on the PBS and as such recommended that flow-on restriction changes to these products were appropriate.
INFLIXIMAB Powder for I.V. infusion 100 mg Inflectra® Pfizer Australia Pty Ltd Change to listing (Minor Submission)	Crohn disease Fistulating Crohn disease Ulcerative colitis Ankylosing spondylitis Psoriatic arthritis Chronic plaque psoriasis	To request an increase in the maximum quantity of vials from 4 to 5 in the Authority Required (STREAMLINED), subsequent continuing treatment phase for indications for which a 5 mg/kg dose regimen is required.	The PBAC recommended an increase in the maximum quantity for the Section 100 (Highly Specialised Drugs) Authority Required (STREAMLINED) listings of infliximab for subsequent continuing treatment from 4 to 5 vials for severe Crohn disease, complex refractory fistulising Crohn disease, moderate to severe Crohn disease, moderate to severe ulcerative colitis, ankylosing spondylitis, severe psoriatic arthritis, and severe chronic plaque psoriasis. The recommended change in maximum quantity would provide sufficient supply for the treatment of patients weighing up to 100 kg.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
IVACAFTOR Sachet containing granules 50 mg Sachet containing granules 75 mg Kalydeco® Vertex Pharmaceuticals (Australia) Pty Ltd Change to listing (Major Submission)	Cystic fibrosis (CF)	To request an extension to the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include the treatment of CF in patients aged 12–24 months who have at least one *G551D* or other gating (class III) mutation in the CF transmembrane conductance regulator (CFTR) gene.	The PBAC recommended extending the Section 100 (Highly Specialised Drugs Program), Authority Required listing of ivacaftor granules to include treatment of patients aged 12 to 24 months who have a *G551D* mutation or other class III gating mutations in the CFTR gene. The PBAC noted that the efficacy data in the 12-24 months age group was limited however, acknowledged the difficulties associated with getting clinical data in this setting. The PBAC considered that based on the overall evidence, a benefit in earlier treatment was biologically plausible. The PBAC considered that any uncertainty in cost-effectiveness could be adequately managed by including this patient population within the current risk sharing arrangements for ivacaftor.
LANREOTIDE Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel® Ipsen Pty Ltd Change to listing (Minor Submission)	Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NETs)	To request a Section 100 (Highly Specialised Drug - Community Access), Authority Required (STREAMLINED) listing for the treatment of GEP-NETs.	The PBAC recommended extending the current listing for lanreotide acetate 120 mg/0.5 mL pre-filled syringes to include a Section 100 (Highly Specialised Drugs Program –Community Access) Authority Required (STREAMLINED) listing for patients receiving continuing treatment for non-functional gastroenteropancreatic neuroendocrine tumour. The PBAC recommended that the initial phase of treatment should remain unchanged under Section 100 (Highly Specialised Drugs Program – Public/Private Hospital).
LEVONORGESTREL Intrauterine drug delivery system 19.5 mg Kyleena® Bayer Australia Ltd New listing (Major Submission)	Contraception	To request a Restricted Benefit listing for contraception.	The PBAC recommended the listing of a new form of levonorgestrel (Kyleena®) as a Restricted Benefit on a cost minimisation basis against a currently listed form of levonorgestrel (Mirena®) at an equivalent price for use in contraception.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
MORPHINE Capsule containing morphine sulfate pentahydrate 10 mg (modified release) Capsule containing morphine sulfate pentahydrate 20 mg (modified release) Kapanol® Mayne Pharma International Pty Ltd Change to listing (Minor Submission)	Chronic breathlessness	To request a Restricted Benefit listing on the Palliative Care schedule for the treatment of chronic breathlessness.	The PBAC recommended extending the PBS-listing of morphine modified release capsules (Kapanol®) on the Palliative Care schedule to include restricted benefit listing for the treatment of patients with chronic breathlessness. The PBAC considered that while the current evidence base to support the use of morphine for breathlessness in palliative care was limited, the Committee was satisfied that morphine provides, for some patients, an improvement in efficacy over conventional care particularly in patients with severe symptoms.
NALOXONE 2.2 mg/actuation nasal spray, 2 x 1 actuation Nyxoid® Mundipharma Pty Ltd New listing (Minor Submission)	Known or suspected opiate overdose	To request an unrestricted benefit listing for known or suspected opiate overdose.	The PBAC recommended the dual General Schedule and Section 100 listing of intranasal naloxone for use in acute opioid overdose. The PBAC considered that there was a public health need to increase use of naloxone to address high rates of opioid overdose, and considered that while the clinical benefits of intranasal naloxone were similar to injectable naloxone, availability of the intranasal formulation could contribute to increasing overall use due to ease of administration. The PBAC considered it would be appropriate to have a dual listing across Section 85 and Section 100 for existing forms of naloxone to enable their inclusion within the Take Home Naloxone pilot program announced by the Hon. Minister Hunt on 27 February 2019.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® Bristol-Myers Squibb Australia Pty Ltd Change to listing (Minor Submission)	Melanoma Non-small cell lung cancer Renal cell carcinoma Squamous cell carcinoma of the head and neck	A request to amend the current 3mg/kg every two weeks (Q2W) dosing regimen of nivolumab for the treatment of unresectable Stage III or Stage IV malignant melanoma to include recent TGA approved changes to dosing and allow clinician choice of either: 1. Weight-based 3mg/kg Q2W dosing, or 2. Fixed 240mg Q2W dosing, or 3. Fixed 480mg every 4 weeks (Q4W) dosing.	The PBAC recommended the addition of two flat dosing regimens (240 mg Q2W and 480 mg Q4W) to the existing 3 mg/kg Q2W weight based dosing regimen for all existing and future PBS indications where nivolumab monotherapy is used. Based on the overall evidence, the PBAC considered that the efficacy and safety of the flat and weight based dosing regimens would likely be comparable. The PBAC considered that while the estimated utilisation split between flat and weight based dosing regimens was uncertain, it was reasonable to assume that the majority of patients would be prescribed the 480 mg Q4W dosing regimen if available. As such, the PBAC considered there would be some cost-savings to Government associated with the addition of nivolumab flat dosing regimens due to reduced infusion administrations.
OCRIPLASMIN Solution for intravitreal injection 0.375 mg in 0.3 mL Jetrea® RTU iCare Pharma Distributors New listing (Minor Submission)	Vitreomacular traction syndrome (VTS)	To request an Authority Required listing of a new form of ocriplasmin for VTS.	The PBAC recommended the Authority Required listing of the new form of ocriplasmin for the treatment of VTS that is intended to replace the existing 0.5mg/0.2mL formulation.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND Powder for I.V. injection containing 250 mg paclitaxel Abraxane® Specialised Therapeutics Pty Ltd New listing (Minor Submission)	Adenocarcinoma of the pancreas Breast cancer	To request an Authority Required (STREAMLINED) listing of a new vial size.	The PBAC recommended the Authority Required (STREAMLINED) listing of a 250 mg vial of nanoparticle albumin-bound paclitaxel (*nab*-paclitaxel) powder for injection under the same conditions as the currently listed *nab*-paclitaxel 100 mg vial, at an equivalent price per mg as the 100 mg vial for its corresponding indications.
PEGVISOMANT Injection set containing powder for injection 10 mg, 30 and diluent, 30 Injection set containing powder for injection 15 mg, 30 and diluent, 30 Injection set containing powder for injection 20 mg, 30 and diluent, 30 Injection set containing powder for injection 20 mg, 1 and diluent, 1 Somavert® Pfizer Australia Pty Ltd Change to listing (Minor Submission)	Acromegaly	To request a change to the definition of failure to achieve biochemical control in the current PBS restriction.	The PBAC recommended the following changes to the definition of failure to achieve biochemical control in the current initial PBS restriction for pegvisomant: • A reduction to the level of growth hormone (GH) from 2.5 mcg/L to 1 mcg/L; • A reduction to the level of insulin-like growth factor 1 (IGF-1) from greater than 1.3 times the age- and sex-adjusted upper limit of normal (ULN) to greater than the age- and sex-adjusted ULN; • A change from using both the GH and IGF-1 criteria to define failure to using either of these criteria; and • To include GH levels in both mcg/L and mIU/L. The PBAC considered that this restriction change should also apply to pasireotide to maintain consistency in eligibility for second-line agents.

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
QUADRIVALENT INFLUENZA VACCINE 0.5 mL pre-filled syringe Fluarix Tetra® GlaxoSmithKline Australia Pty Ltd Change to listing (Minor Submission)	Influenza	To request an extension of the National Immunisation Program listing of the Fluarix® Tetra brand to include children aged 6 months to 3 years of age.	The PBAC recommended an extension to the listing of Fluarix Tetra® (quadrivalent influenza vaccine (split virion, inactivated)), on the National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1) (the Determination), for the prevention of seasonal influenza to include high risk and Aboriginal and/or Torres Strait Islander infants and children aged 6 to 35 months of age, noting the current Fluarix Tetra listing is for patients over 3 years of age. The PBAC noted that there are benefits to a single vaccine that covers both adults and children, compared to the current NIP listing that only includes separate child and adult products. Based on the evidence presented, the PBAC considered that Fluarix Tetra was cost-effective on a cost-minimisation basis to FluQuadri Junior. The recommended change would provide a single influenza vaccine for infants, children and adults.
RITUXIMAB Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL Truxima® Celltrion Healthcare Australia Pty. Ltd. New listing (Minor Submission)	Non-Hodgkin lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar rituximab for the treatment of CD20 positive B-cell non-Hodgkin lymphoma under the same conditions as the reference biologic.	The PBAC recommended the listing of the biosimilar brand of rituximab, Truxima®, under Section 100 (Efficient Funding of Chemotherapy) as an Authority Required (STREAMLINED) listing for the treatment of stage III or IV CD20 positive follicular B-cell non-Hodgkins lymphoma (NHL). The PBAC advised that the Truxima, MabThera and Riximyo brands of rituximab should be considered equivalent for the purpose of substitution (i.e., 'a' flagged). The PBAC noted four brands of the rituximab biosimilar are TGA registered by the same sponsor, including Tuxella®, Rituzena®, Ritemvia® in addition to Truxima, for different sets of indications. The PBAC advised that although the submission only requested listing of Truxima for NHL indications, in principle, the Truxima brand (and other brands of the identical biosimilar rituximab sponsored by Celltrion Healthcare) could be recommended for all TGA registered indications for which the reference brand Mabthera is currently listed on the PBS. Where multiple brands of an identical biosimilar are marketed by the same sponsor, the PBAC stated a preference for a single brand of the same biosimilar rituximab to be PBS listed for all indications for which the reference biologic is currently PBS listed (where TGA registered for all indications), to minimise the risks of quality use of medicines issues such as patient and prescriber confusion, where a change in brand is incorrectly considered a treatment switch.

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SEVELAMER Tablet containing sevelamer carbonate 800 mg Sevelamer Dr Reddy's® Dr Reddy's New listing (Minor Submission)	Hyperphosphataemia	To request Section 100 (Highly Specialised Drug Program) and Section 85 Authority Required (STREAMLINED) listings for the treatment of hyperphosphataemia in adult patients with chronic kidney disease who are on dialysis.	The PBAC recommended the listing of a new form of sevelamer (as carbonate) on the General Schedule and under Section 100 (Highly Specialised Drugs Program) as an Authority Required (STREAMLINED) listing for hyperphosphataemia in patients undergoing dialysis for chronic kidney disease. The PBAC considered that sevelamer carbonate 800 mg tablets were therapeutically equivalent (and bioequivalent) to sevelamer hydrochloride 800 mg tablets at the recommended doses. The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, the Renagel® and Sevelamer Dr Reddy's brands could be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution at the pharmacy level ('a' flagged).
TEDUGLUTIDE Powder for injection 5 mg with diluent Revestive® Shire Australia Pty Limited New listing (Major Submission)	Short Bowel Syndrome (SBS)	Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required listing for the treatment of SBS in patients who are dependent on parenteral nutrition for survival.	The PBAC recommended the listing of teduglutide as a Section 100 (Highly Specialised Drug Program) Authority Required benefit for the treatment of patients with Type III (chronic) intestinal failure associated with SBS. The PBAC recognised the high clinical need in this small patient group, and considered that teduglutide may reduce the patient burden associated with the current therapy, parenteral support. The PBAC considered that, with the revised restriction informed by clinicians, and the risk sharing arrangement proposed, teduglutide was cost-effective compared with standard care. The PBAC noted the consumer comments that outlined the detrimental quality of life impact associated with parenteral support particularly due to the significant time impact, immobility while connected to parenteral support, dehydration, lack of energy and the social and carer impacts. The PBAC considered that, for some patients, teduglutide would result in a clinically meaningful reduction in the number of days per week of parenteral support. The PBAC considered that teduglutide treatment should be confined to those patients most likely to achieve a clinically meaningful benefit, with the treatment duration limited to that necessary to achieve such benefits.
TEZACAFTOR with IVACAFTOR Tablet containing tezacaftor 100 mg with ivacaftor 150 mg	Cystic fibrosis (CF)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of CF in patients aged over 12 years:	*(a) patients aged over 12 years who are homozygous for the F508del mutation in the CFTR gene* The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required listing of tezacaftor with ivacaftor for the treatment of

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Symdeko® Vertex Pharmaceuticals (Australia) Pty Ltd New listing (Major Submission)		a) who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator (CFTR) gene; and b) who have at least one residual function (RF) mutation in the CF transmembrane conductance regulator (CFTR) gene.	patients aged 12 years and older who are homozygous for the *F508del* mutation in the CFTR gene on a cost-minimisation basis to lumacaftor with ivacaftor. The PBAC considered that, consistent with the evidence presented and the claim of non-inferior comparative effectiveness and safety, the price paid for tezacaftor with ivacaftor should be no higher than the price per patient per year at which it previously recommended lumacaftor with ivacaftor. The PBAC further advised that tezacaftor with ivacaftor should be listed under the same Managed Access Program arrangements for lumacaftor with ivacaftor and with no additional cost to Government. *(b) patients aged over 12 years who have at least one RF mutation in the CFTR gene* The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required listing of tezacaftor with ivacaftor for the treatment of patients aged 12 years or older who have one copy of the *F508del* mutation and one mutation that is responsive to tezacaftor with ivacaftor (referred to as an RF mutation) in the CFTR gene. Overall, the PBAC considered the claim of superior efficacy compared with best supportive care (BSC) was adequately supported in the short-term on the basis of the primary outcome in Study 108 which indicated an increase from baseline in per cent predicted forced expiratory volume in one second (ppFEV1) for patients treated with tezacaftor with ivacaftor compared with BSC of 6.8% (95% CI: 5.7, 7.8) after 8 weeks of treatment. An interim analysis of extension data from Study 110 indicated that this increase was maintained for an additional 16 weeks of treatment. However, the PBAC noted that given the short duration of follow-up, it was unknown whether the observed improvement in ppFEV1 would be maintained in the long-term, particularly in the context of a lifelong progressive disease. The PBAC also noted that Study 108 demonstrated an improvement in quality of life compared with BSC after 8 weeks of treatment; however, it was uncertain whether this difference would be maintained over the long-term. There was insufficient clinical evidence to determine if treatment with

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			tezacaftor with ivacaftor for the RF mutation patient population would be associated with improvements in life expectancy, nutritional status (including weight and height) or reduction in pulmonary exacerbations or the need for other medications. However, the PBAC acknowledged the high clinical need for therapy for this patient population and considered there is a clinical place for this medicine at a price commensurate with its potential clinical benefits. The PBAC considered the assumptions around the long-term efficacy of tezacaftor with ivacaftor in the economic model and the resulting incremental cost-effectiveness ratio compared with BSC to be uncertain. The PBAC advised that the cost effectiveness of tezacaftor with ivacaftor would likely be no worse than that for lumacaftor with ivacaftor for patients who are homozygous for the F508del mutation if the price per patient per year for tezacaftor with ivacaftor was no higher than that previously recommended for lumacaftor with ivacaftor. The PBAC further advised that the financial arrangements and other terms of the existing Managed Access Program for lumacaftor with ivacaftor would be required to apply equally to tezacaftor with ivacaftor to manage the uncertain cost-effectiveness of tezacaftor with ivacaftor in this treatment setting.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TIOTROPIUM Capsule containing powder for oral inhalation 13 microgram (for use in Zonda device) Braltus® TEVA Australia Pty Ltd New listing (Minor Submission)	Chronic obstructive pulmonary disease (COPD)	To request a Restricted Benefit listing for the treatment of COPD.	The PBAC recommended the Section 85 Restricted Benefit listing of a new brand of tiotropium, Braltus® as an alternative brand to the currently listed brand Spiriva®. The PBAC noted two main differences between the Braltus® and Spiriva® products: both Braltus® and Spiriva® deliver the same dose of active substance to the patient (10 microgram per capsule) but have a different labelled metered dose (13 and 18 microgram per capsule respectively); Braltus® is delivered via a Zonda® device whereas Spiriva® is delivered via a HandiHaler device®. The PBAC noted that the TGA has accepted that bioequivalence has been established between the Braltus® and Spiriva® products, and as such the PBAC recommended that the Braltus® and the Spiriva® products are to be treated as equivalent (i.e. “a” flagging) in the Schedule of Pharmaceutical Benefits. The PBAC considered the differences in the labelled metered dose and devices could be managed in the course of the regular patient education and counselling on the use of the devices that is provided to patients by prescribers and pharmacists. The PBAC considered that the information and education measures proposed by the sponsor had addressed key Quality Use of Medicine concerns regarding the two main differences between the Braltus® and Spiriva® products.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TOCILIZUMAB Injection 162 mg in 0.9 mL single use pre-filled pen Injection 162 mg in 0.9 mL single use pre-filled syringe Actemra® Roche Products Pty Ltd Change to listing (Minor Submission)	Polyarticular juvenile idiopathic arthritis.	To request an extension of the current Authority Required listing of subcutaneous tocilizumab to include polyarticular juvenile idiopathic arthritis.	The PBAC recommended extending the PBS-listing of subcutaneous tocilizumab to include an Authority Required listing for the treatment of severe active polyarticular juvenile idiopathic arthritis on a cost-minimisation basis to intravenous tocilizumab. The PBAC considered based on the evidence presented, that subcutaneous tocilizumab was likely to be equivalent in efficacy and safety to IV tocilizumab.
TOCILIZUMAB Injection 162 mg in 0.9 mL single use pre-filled pen Actemra® Roche Products Pty Ltd Change to listing (Minor Submission)	Giant cell arteritis	Resubmission to request an Authority Required listing for the treatment of giant cell arteritis.	The PBAC recommended the Authority Required listing of tocilizumab for the treatment of patients with giant cell arteritis. The PBAC considered that the minor resubmission had adequately addressed its concerns from November 2018 by revising the restriction and the financial estimates and including a proposal for a Risk Sharing Agreement. The PBAC was satisfied that tocilizumab provides, for some patients, a significant improvement in efficacy over standard of care. The PBAC reiterated its previous advice that there is a high unmet clinical need for effective treatments for giant cell arteritis particularly given the adverse events associated with corticosteroids in this population who are often older patients with comorbidities, and the limited treatment options available.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TOFACITINIB Tablet 5 mg Tablet 10 mg Xeljanz® Pfizer Australia Pty Ltd Change to listing (Major Submission)	Ulcerative Colitis (UC)	To request an Authority Required listing for the treatment of moderate to severe UC in adult patients who have had an inadequate response or failure of standard medical management (5-aminosalicylates [5-ASAs], thiopurines and/or a course of corticosteroids) according to the Mayo endoscopy score, or intolerance to these treatments.	The PBAC recommended the Authority Required listing of tofacitinib on a cost minimisation basis against the least costly biologic therapy for moderate to severe UC.
TRASTUZUMAB Powder for I.V. infusion 150 mg Powder for I.V. infusion 440 mg with diluent Ogivri® Alphapharm Pty Ltd New listing (Minor Submission)	Breast cancer Gastric cancer	To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.	The PBAC recommended the listing of the biosimilar brand of trastuzumab, Ogivri, on the Section 100 (Efficient Funding of Chemotherapy Program), for all indications for which the trastuzumab reference brand (Herceptin) is currently PBS-listed. The PBAC advised that the Herceptin, Ogivri and Ontruzant brands of trastuzumab should be considered equivalent for the purpose of substitution (i.e. 'a' flagged) and considered the application of biosimilar uptake drivers was reasonable. The PBAC recommended that all listings of trastuzumab could be changed to Authority Required (Streamlined), however PBS listings for other agents used in metastatic breast cancer (pertuzumab, trastuzumab emtansine and lapatinib) should remain written authority required.

MARCH 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TRASTUZUMAB Powder for I.V. infusion 150 mg Ontruzant® Merck Sharp & Dohme (Australia) Pty Limited New listing (Minor Submission)	Breast cancer Gastric cancer	To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.	The PBAC recommended the listing of the biosimilar brand of trastuzumab, Ontruzant, on the Section 100 (Efficient Funding of Chemotherapy Program), for all indications for which the trastuzumab reference brand (Herceptin) is currently PBS-listed. The PBAC advised that the Herceptin, Ontruzant and Ogivri brands of trastuzumab should be considered equivalent for the purpose of substitution (i.e. 'a' flagged) and considered the application of biosimilar uptake drivers was reasonable. The PBAC recommended that all listings of trastuzumab could be changed to Authority Required (Streamlined), however PBS listings for other agents used in metastatic breast cancer (pertuzumab, trastuzumab emtansine and lapatinib) should remain written authority required.
TRIGLYCERIDES - MEDIUM CHAIN, FORMULA Oral liquid 500mL, 12 (Nutrini Peptisorb) Oral liquid 500 mL, 12 (Nutrini Peptisorb Energy) Nutrini Peptisorb® Nutrini Peptisorb Energy® Nutricia Australia Pty Limited Change to listing (Minor Submission)	Dietary management of conditions requiring a source of medium chain triglycerides	To request a change to the pack size and maximum quantities of Nutrini Peptisorb and Nutrini Peptisorb Energy.	The PBAC agreed with the change to the pack sizes and associated maximum quantities for triglycerides and protein formulas (Nutrini Peptisorb® and Nutrini Peptisorb Energy®) processed by the Secretariat at the same price per gram of energy equivalence as the current listing. Due to the reduction in maximum volume per prescription of Nutrini Peptisorb®, the PBAC requested the Department monitor utilisation 12 months following listing to ensure patients are receiving adequate supply.