NOVEMBER 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ADALIMUMAB Injection 40 mg pre-filled pen: Injection 40 mg pre-filled syringe; Injection 40 mg vial Idacio® Fresenius Kabi Australia Pty Limited New Listing (Minor Submission)	Severe Crohn disease; moderate to severe ulcerative colitis; Severe active juvenile idiopathic arthritis; Complex refractory fistulising Crohn disease; Severe active rheumatoid arthritis; Severe psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Moderate to severe hidradenitis suppurativa	To request an Authority Required (STREAMLINED) listing of a new biosimilar adalimumab under the same conditions as the reference biologic.	The PBAC recommended the listing of the biosimilar brand of adalimumab (Idacio®) pre-filled pen and pre-filled syringe, for the same indications as the reference brand Humira® except for certain paediatric indications, on the basis of a cost-minimisation to Humira. The PBAC did not recommend the listing of the vial as it considered that there was not a sufficient clinical need to support the listing given the 20 mg/0.4 mL syringe was currently available for paediatric listings. The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953,* in the Schedule of Pharmaceutical Benefits, Idacio, Amgevita®, Hadlima®, Hyrimoz® and Humira pre-filled syringes should be treated as equivalent ('a' flagged) to each other; and Idacio, Amgevita, Hadlima, Hyrimoz and Humira pre-filled pens should be treated as equivalent ('a' flagged), for respective PBS-listed indications. The PBAC advised that the biosimilar uptake drivers should be applied to Idacio, consistent with previous recommendations regarding the application of the drivers to other biosimilar brands of adalimumab.
AMINO ACID FORMULA WITH VITAMINS, AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN Sachets containing oral powder 24 g; Sachets containing oral powder 25 g GA Gel® GA Express 15® Vitaflo Australia Pty Limit New listing (Minor Submission)	Pyridoxine dependent epilepsy	To request a Restricted Benefit listing for the management of pyridoxine dependent epilepsy.	The PBAC recommended the listing of GA Gel® and GA Express15® for the dietary management of pyridoxine dependent epilepsy at the same price per gram of protein equivalent as the currently listed GA Gel and GA Express.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
APOMORPHINE Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe Movapo PFS® Stada Pharmaceuticals Australia Pty Limited Change to listing (Minor Submission)	Parkinson's disease	To request General Schedule, Authority Required (STREAMLINED) listing for the continuing treatment of Parkinson's disease following initiation with the current Section 100 (Highly Specialised Drugs Program) listings.	The PBAC recommended an extension to the current listing of apomorphine 50 mg in 10 mL solution for subcutaneous infusion pre-filled syringe (Movapo® PFS) for the treatment of Parkinson's disease. The PBAC considered that, to ensure consistency across all of the apomorphine items on the PBS, it would be reasonable for the current listings of apomorphine 20 mg/2 mL and 50 mg/5 mL ampoules (Movapo®) to also be extended to include General Schedule Authority Required (STREAMLINED) listings for maintenance therapy. The PBAC reiterated its previous advice that the additional listing of these items in the General Schedule should be cost neutral to government.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BECLOMETASONE DIPROPIONATE + FORMOTEROL FUMARATE DIHYDRATE + GYLCOPYRRONIUM Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses Trimbow® Chiesi Australia Pty Ltd New listing (Major Submission)	Chronic obstructive pulmonary disease (COPD)	To request an Authority Required (STREAMLINED) listing for maintenance treatment of moderate to severe COPD.	The PBAC recommended the Authority Required (STREAMLINED) listing of the fixed dose combination (FDC) of beclometasone (BEC) with formoterol (FOR) and glycopyrronium (GLY), Trimbow®, for maintenance treatment of moderate to severe COPD that is not adequately treated by a combination of an inhaled corticosteroid (ICS) with long-acting beta2-agonist (LABA) or LABA with a long-acting muscarinic antagonist (LAMA). The PBAC considered that the claim of non-inferior effectiveness and safety to the FDC of fluticasone furoate (FF), umeclidinium (UMEC) and vilanterol (VIL), Trelegy Ellipta®, was reasonable. However, the PBAC considered for the purposes of satisfying Section 101(3B) of the *National Health Act 1953*, both Trelegy Ellipta, as well as any triple combination therapy via concomitant use of a LAMA, LABA and ICS are relevant alternative therapies. The PBAC's recommendation was therefore, among other matters, based on its assessment that the cost of Trimbow should be no greater than the lowest price combination of the PBS listed components of the triple therapy that are available for COPD. The PBAC accepted the following equi-effective doses as the basis for the cost-minimisation analysis: Trimbow (BEC/FOR/GLY) 100 mcg/ 6mcg/10 mcg two actuations twice daily = Trelegy Ellipta (FF/UMEC/VI) 100 mcg /62.5 mcg /25 mcg one actuation once daily.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BEVACIZUMAB Solution for I.V. infusion 100 mg in 4 mL; Solution for I.V. infusion 400 mg in 16 mL Mvasi® Amgen Australia Pty Limited New listing (Minor Submission)	Metastatic colorectal cancer (mCRC); advanced stage IIIB, IIIC or stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; advanced carcinoma of the cervix; stage IV (metastatic) non-small cell lung cancer (NSCLC); relapsed or recurrent glioblastoma	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new biosimilar bevacizumab under the same conditions as the reference biologic.	The PBAC recommended the listing of bevacizumab (Mvasi®) as a biosimilar brand of bevacizumab (Avastin®) on a cost-minimisation basis for all of the indications for which Avastin is currently PBS listed. Consistent with Avastin, the PBAC recommended an Authority Required (STREAMLINED) listing for all indications except for relapsed or recurrent glioblastoma, which is currently a written (delayed assessment) authority for initial treatment and telephone/online (immediate) authority for continuing treatment. The PBAC noted that Efficient Funding of Chemotherapy medicines are governed by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*, and that Section 33(2) allows substitution of brands under the same item code.
CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® Ipsen Pty Ltd Change to listing (Major Submission)	Renal cell carcinoma (RCC)	Resubmission to request an extension to the current Authority Required (STREAMLINED) listing for the treatment of Stage IV clear cell variant RCC to include patients who have not been previously treated with a tyrosine kinase inhibitor (TKI).	The PBAC recommended extending the existing listing of cabozantinib to include the treatment of patients with stage IV clear cell variant RCC who have not previously been treated with a TKI. The PBAC was satisfied that cabozantinib provides, for some patients, an improvement in progression free survival versus sunitinib, however the PBAC considered that an improvement in overall survival was not supported by the evidence presented. The PBAC considered that cabozantinib would be acceptably cost-effective in the new indication if the cost per day is no higher than the average cost per day for sunitinib. The PBAC considered that the resubmission had overestimated the weighted price (across the new and existing indications) and risk sharing arrangement utilisation caps.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
CANNABIDIOL Oral solution, 100 mg per mL, 100 mL Epidyolex® Emerge Health Pty Ltd New listing (Major Submission)	Lennox-Gastaut syndrome; Dravet syndrome	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the adjunctive treatment of seizures in patients with Lennox-Gastaut syndrome or Dravet syndrome in patients aged 2 years or older.	The PBAC recommended the listing of cannabidiol for the treatment of Dravet Syndrome in combination with at least two other anti-epileptic drugs (AEDs) on the PBS. The PBAC considered the appropriate place in therapy for cannabidiol is as a third line treatment and that cannabidiol was likely to be cost-effective at a cost per patient per year that is less than, or is not significantly higher than, that for stiripentol. The PBAC considered the financial impact could be reliably estimated based on the number of eligible patients in this small, well defined population. The PBAC did not recommend the listing of cannabidiol for treatment of Lennox Gastaut Syndrome (LGS) in combination with other AEDs on the PBS. The PBAC considered the appropriate place in therapy for cannabidiol is as a third line treatment but the cost-effectiveness of cannabidiol for LGS remained uncertain. The PBAC considered the financial estimates provided in the submission were high and uncertain and that further information was required to appropriately define this potentially large, heterogeneous patient population.
CARIPRAZINE Capsule 1.5 mg Capsule 3 mg Capsule 4.5 mg Capsule 6 mg Reagila® Seqirus (Australia) Pty Ltd New listing (Major Submission)	Schizophrenia	To request an Authority Required (STREAMLINED) listing for the treatment of schizophrenia.	The PBAC recommended the listing of cariprazine (Reagila®) for the treatment of schizophrenia. The PBAC considered that the claims of non-inferior effectiveness and safety to aripiprazole and brexpiprazole were reasonable. The PBAC's recommendation for listing was, among other matters, based on its assessment that the cost of cariprazine should be no greater than the lowest price alternative therapy. The PBAC considered the cost-minimisation analysis should be based on the following equi-effective doses: cariprazine 5 mg per day and brexpiprazole 3.58 mg per day.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DEFERASIROX Dispersible tablet 125 mg Dispersible tablet 250 mg Dispersible tablet 500 mg Deferasirox Juno® Juno Pharmaceuticals Pty Ltd New listing (Minor Submission)	Chronic iron overload	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for a new form of deferasirox for the treatment of chronic iron overload.	The PBAC recommended the listing of Deferasirox Juno® for patients with chronic iron overload due to disorders of haemopoiesis on a cost-minimisation basis to Jadenu®, and reaffirmed its view that deferasirox dispersible tablets are biocomparable to deferasirox film-coated tablets.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DUPILUMAB Injection 200 mg in 1.14 mL single use prefilled syringe; Injection 300 mg in 2 mL single use pre-filled syringe Dupixent® Sanofi-Aventis Australia Pty Ltd Change to listing (Major Submission)	Asthma	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe uncontrolled asthma.	The PBAC recommended the Section 100 Highly Specialised Drug Program Authority Required (Written) listing of dupilumab for the treatment of uncontrolled severe eosinophilic or allergic asthma, both with and without oral corticosteroid (OCS) dependence. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of dupilumab would be acceptable if it were cost-minimised against the least costly biologic for asthma over a 1-year time frame. Thus, the PBAC considered the equi-effective doses for eosinophilic asthma were: • dupilumab 400 mg subcutaneous injection followed by 200 mg given every 2 weeks in the non-OCS dependent population (27 doses over one year); and • dupilumab 600 mg subcutaneous injection followed by 300 mg given every 2 weeks in the OCS dependent population (27 doses over one year); and • benralizumab 30 mg subcutaneous injection every 4 weeks for the first three doses, and every 8 weeks thereafter (7.5 doses over one year), and • mepolizumab 100 mg subcutaneous injection every 4 weeks (13 doses over one year). The PBAC considered the equi-effective doses in patients with allergic asthma were: • dupilumab 400 mg subcutaneous injection followed by 200 mg given every 2 weeks in the non-OCS dependent population (27 doses over one year); and • dupilumab 600 mg subcutaneous injection followed by 300 mg given every 2 weeks in the OCS dependent population (27 doses over one year); and • omalizumab 398 mg every 4 weeks subcutaneous injection, either as one dose or split into two equal doses depending on patient weight and IgE level (13 doses over one year).

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DURVALUMAB Solution concentrate for I.V. infusion 120 mg in 2.4 mL; Solution concentrate for I.V. infusion 500 mg in 10 mL Imfinzi® AstraZeneca Pty Ltd Change to listing (Major Submission)	Small cell lung cancer (SCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing in combination with etoposide and platinum-based chemotherapy for the first-line treatment of extensive-stage SCLC.	The PBAC recommended the listing of durvalumab, for patients with extensive stage SCLC. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of durvalumab would be acceptable if it were cost-minimised against atezolizumab, based on the equivalent dosing regimen.
GUSELKUMAB Injection 100 mg in 1 mL single use pre-filled syringe; Injection 100 mg in 1 mL single use pre-filled pen Tremfya® Janssen-Cilag Pty Ltd Change to listing (Major Submission)	Psoriatic arthritis (PsA)	To request an Authority Required (Written) listing for the treatment of adult patients with severe PsA who have had an inadequate response to methotrexate and sulfasalazine or leflunomide.	The PBAC recommended the listing for guselkumab on a cost minimisation basis with the least costly biological disease modifying anti-rheumatic drug (bDMARD) for severe PsA. In making this recommendation, the PBAC accepted that any of the currently PBS listed bDMARDs for severe PsA could be an alternative therapy to guselkumab. The PBAC considered that guselkumab must be less expensive than the 'higher tier' bDMARDs to account for the lack of evidence to support non-inferiority to the higher tier medicines, and could not be any more costly than any of the 'lower tier' bDMARDs currently listed on the PBS for this condition.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE Oral liquid 250 mL, 30 KetoVie 4:1® KetoVie 3:1® KetoVie Peptide 4:1® Cortex Health Pty Ltd New listing (Minor Submission)	Ketogenic diet	To request a Restricted Benefit listing for KetoVie 4:1 and 3:1 and an Authority Required (STREAMLINED) listing for KetoVie Peptide 4:1 as part of a ketogenic diet.	The PBAC recommended the listing of KetoVie 3:1®, KetoVie 4:1® and KetoVie Peptide 4:1® for ketogenic diet on a cost-minimisation basis and at the same price per kilojoule as KetoCal 3:1 and KetoCal 4:1 at the approved ex-manufacturer price.
IBRUTINIB Tablet 140 mg Tablet 280 mg Tablet 420 mg Tablet 560 mg Imbruvica® Janssen-Cilag Pty Ltd New listing (Minor Submission)	Chronic lymphocytic leukaemia (CLL); small lymphocytic lymphoma (SLL); mantle cell lymphoma	To request an Authority Required listing of ibrutinib tablet under the same conditions as the already listed capsule.	The PBAC recommended the listing of ibrutinib 140 mg, 280 mg, 420 mg and 560 mg tablets, for the treatment of patients with refractory or relapsed CLL or SLL and mantle cell lymphoma under the same conditions as the currently listed ibrutinib 140 mg capsules. The PBAC considered the proposed price of ibrutinib tablets, which was based on the same cost per milligram as the 140 mg capsules, was appropriate. The PBAC considered that the equi-effective doses were ibrutinib 140 mg tablet and ibrutinib 140 mg capsule. The PBAC considered that the listing of various strengths of ibrutinib tablets would reduce the pill burden for some patients.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
INFLIXIMAB Injection 120 mg in 1 mL pre-filled syringe; Injection 120 mg in 1 mL pre-filled pen Remsima® SC Celltrion Healthcare Australia Pty Ltd New listing (Major Submission)	Rheumatoid arthritis Ankylosing spondylitis Psoriatic arthritis Chronic plaque psoriasis Crohn's disease Complex refractory fistulising Crohn disease Ulcerative colitis	To request Section 100 (Highly Specialised Drugs Program) and Authority Required listings under the same conditions as infliximab powder for I.V. infusion 100 mg.	The PBAC recommended the listing of infliximab (IFX) SC on the General Schedule (Section 85), for the treatment of severe active rheumatoid arthritis (RA), moderate to severe ulcerative colitis (UC) and severe refractory Crohn's disease (CD) on a cost minimisation basis to IFX IV. The PBAC advised that the listing of IFX SC should be based on the equi-effective dose of IFX SC 120 mg every 2 weeks and (i) IFX IV 3 mg/kg mg every 8 weeks in RA; and (ii) IFX IV 5 mg/kg every 8 weeks in UC and CD. The PBAC did not consider extrapolation of clinical evidence from RA, UC and CD to ankylosing spondylitis (AS), severe active psoriatic arthritis (PsA), severe chronic plaque psoriasis (CPP) and complex refractory fistulising Crohn's disease (RFCD) was adequate to support PBS listings for AS, PsA, CPP and RFCD. The PBAC noted there were no clinical trials assessing the efficacy of IFX SC in patients with these conditions, and considered it could not be assumed that IFX SC would be non-inferior to IFX IV given the higher dose of IFX IV is recommended in PsA, CPP and RFCD (5 mg/kg every 8 weeks) and the higher dose is recommended with more frequent administration in AS (5 mg/kg every 6 weeks).
MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE Injection 0.5 mL MenQuadfi® Sanofi-Aventis Australia Pty Ltd New listing (Major Submission)	Prevention of meningococcal disease	To request National Immunisation Program (NIP) listing for the prevention of meningococcal disease in toddler and adolescent populations.	The PBAC recommended that MenQuadfi® (a quadrivalent meningococcal vaccine) be a designated vaccine for the purposes of the *National Health Act*, for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W135, and Y, for children aged 12 months, adolescents aged 14 to 19 years, and at-risk individuals who are 12 months of age and older and are currently eligible for Nimenrix® (another quadrivalent meningococcal vaccine) through the National Immunisation Program, under the same provisions. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of MenQuadfi would be acceptable if it were cost-minimised against Nimenrix.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
MESALAZINE Tablet 1600 mg Asacol® Chiesi Australia Pty Ltd New listing (Minor Submission)	Ulcerative colitis	To request a Restricted Benefit listing of mesalazine for the treatment of mild to moderate ulcerative colitis and maintenance of remission in adults.	The PBAC recommended the listing of mesalazine 1600 mg enteric coated tablets (Asacol 1600) for the treatment of ulcerative colitis. The PBAC recommended the listing of Asacol 1600 on a cost-minimisation basis based on the price per mg of the currently PBS listed mesalazine 800 mg enteric coated tablets (Asacol 800). The equi-effective doses are: one Asacol 1600 tablet and two Asacol 800 tablets.
NIVOLUMAB IPILIMUMAB Nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® Ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy® Bristol-Myers Squibb Australia Pty Ltd Change to listing (Major Submission)	Non-small cell lung cancer (NSCLC)	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing in combination with two cycles of chemotherapy for the first-line treatment of patients with Stage IV (metastatic) NSCLC.	The PBAC recommended the listing of nivolumab plus ipilimumab in combination with two cycles of platinum-based doublet chemotherapy (NIVO+IPI+platinum) for the treatment of previously untreated Stage IV NSCLC, limited to the squamous population only, on the basis that it should be available only under special arrangements under Section 100. The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of NIVO+IPI+platinum would be acceptable if it were cost-minimised against pembrolizumab in combination with platinum-based doublet chemotherapy (pembrolizumab+platinum). The PBAC did not recommend NIVO+IPI+platinum for the treatment of previously untreated Stage IV non-squamous NSCLC. The PBAC considered the clinical claim that NIVO+IPI+platinum is non-inferior to pembrolizumab+platinum for efficacy and safety in non-squamous NSCLC was not supported by the clinical evidence presented and therefore a cost-minimisation analysis in this population was not appropriate.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
PANCREATIC EXTRACT Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity Capsule (containing enteric coated minimicrospheres) providing not less than 35,000 BP units of lipase activity Creon® Mylan Health Pty Ltd New listing (Minor Submission)	Pancreatic exocrine insufficiency	To request an Unrestricted Benefit listing under the same conditions as the already listed strengths.	The PBAC recommended the listing of two new strengths of pancreatic extract (Creon®), 20,000 and 35,000 lipase BP units modified release capsules, under the same conditions as the currently PBS listed Creon products.
PROGESTERONE Capsule 200 mg Utrogestan® Besins Healthcare Australia Pty Ltd Change to listing (Major Submission)	Prevention of preterm birth	To request an extension of the current Authority Required (STREAMLINED) listing to include the prevention of preterm birth in women at risk.	The PBAC recommended the listing of progesterone (Utrogestan®) for the prevention of preterm birth in women with singleton pregnancies and a short cervix (≤25 mm) and/or a history of preterm birth. The PBAC considered that while the benefit of progesterone may have been overstated by the sponsor, it was reasonable to accept that progesterone is associated with a risk reduction in preterm birth. The PBAC noted that the use of progesterone was consistent with international clinical guidelines and recognised that access should be equitable for all women in the target population. The PBAC noted that the reduction in pre-term births and the hospitalisation costs assumed in the cost analysis were very uncertain. However, the PBAC also noted that the cost of progesterone per pregnancy was small in comparison to the potential saving from hospital admissions for pre-term births, and considered Utrogestan to be acceptably cost-effective at the price proposed in the submission. The PBAC considered that the projected utilisation of progesterone was highly uncertain, and could be addressed by a risk sharing arrangement.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
PROGESTERONE Pessary 200 mg Oripro® Orion Laboratories Pty Ltd Change to listing (Major Submission)	Prevention of preterm birth	To request an extension of the current Authority Required (STREAMLINED) listing to include the prevention of preterm birth in women at risk.	The PBAC recommended the listing of progesterone (Oripro®) for the prevention of preterm birth in women with singleton pregnancies and a short cervix (≤25 mm) and/or a history of preterm birth. The PBAC considered that while the benefit may have been overstated by the sponsor, it was reasonable to accept that progesterone is associated with a risk reduction in preterm birth. The PBAC noted that the use of progesterone was consistent with international clinical guidelines and recognised that access should be equitable for all women in the target population. The PBAC considered that Oripro would be cost-effective if it was cost-minimised against Utrogestan®. The PBAC considered that the projected utilisation of progesterone was highly uncertain, and could be addressed by a risk sharing arrangement.
RIBOCICLIB Tablet 200 mg Kisqali® Novartis Pharmaceuticals Australia Pty Ltd Change to listing (Minor Submission)	Locally advanced or metastatic breast cancer	Resubmission to request an Authority Required listing for the treatment of postmenopausal women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer in combination with fulvestrant.	The PBAC recommended the listing of ribociclib, in combination with fulvestrant for the treatment of patients with HR+, HER2- unresectable advanced or metastatic breast cancer. The PBAC previously recognised the clinical need for ribociclib in combination with fulvestrant but deferred making a recommendation in order to resolve the appropriate weighted price, financial impact and changes to risk sharing arrangements for ribociclib. The PBAC considered that these issues were appropriately addressed in the minor resubmission.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
SECUKINUMAB Injection 150 mg in 1 mL pre-filled pen Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd Change to listing (Major Submission)	Non-radiographic axial spondyloarthritis (nr-axSpA)	To request an Authority Required (Written) listing for the treatment of nr-axSpA.	The PBAC recommended the listing of secukinumab for the treatment of nr-axSpA. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of secukinumab would be acceptable if it were cost-minimised to the lowest cost biologic disease-modifying anti-rheumatic drug (bDMARD) for this indication. The PBAC advised the equi-effective doses were: - secukinumab 150 mg at Week 0, 1, 2, 3 and 4, then 150 mg every 4 weeks; or secukinumab 150 mg every 4 weeks - golimumab 50 mg every 4 weeks - certolizumab pegol 400 mg at Week 0, 2, 4, then 200 mg every 2 weeks; or certolizumab pegol 400 mg every 4 weeks.
TOFACITINIB Tablet 5 mg Tablet 10 mg Xeljanz® Pfizer Australia Pty Ltd Change to listing (Major Submission)	Ulcerative colitis and other listed indications	Resubmission to request an Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis.	The PBAC replaced its previous recommendation, made at its March 2019 meeting, for tofacitinib in moderate-to-severe ulcerative colitis (MSUC). The PBAC's revised recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of tofacitinib would be acceptable if it were cost minimised with the least costly biological therapy out of infliximab, golimumab or vedolizumab. The PBAC accepted that tofacitinib is likely of non-inferior safety and efficacy to these agents on the basis of the presented evidence, and that there is sufficient basis to conclude that tofacitinib, for some patients, provides a significant improvement in efficacy in the induction phase compared to adalimumab, based on the evidence provided.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
VEDOLIZUMAB Injection 108 mg in 0.68 mL pre-filled syringe; Injection 108 mg in 0.68 mL pre-filled pen Entyvio® Takeda Pharmaceuticals Australia Pty Ltd New listing (Major Submission)	Ulcerative colitis Crohn's disease	To request Authority Required listings under the same conditions as vedolizumab powder for injection 300 mg.	The PBAC recommended the listing of vedolizumab (VDZ) SC for the treatment of moderate-to-severe ulcerative colitis and severe Crohn's disease on a cost minimisation basis to VDZ IV. The PBAC advised that the listing of VDZ SC be based on the equi-effective dose of VDZ SC 108 mg every 2 weeks and VDZ IV 300 mg every 8 weeks.