

MARCH 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ACALABRUTINIB</p> <p>Capsule 100 mg</p> <p>Calquence®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p>	<p>To request an Authority Required listing for the treatment of patients with relapsed or refractory CLL or SLL considered unsuitable for treatment with a purine analogue.</p>	<p>The PBAC recommended the listing of acalabrutinib for the treatment of patients with relapsed or refractory CLL/SLL considered unsuitable for treatment or retreatment with a purine analogue (also known as second-line treatment of CLL/SLL).</p> <p>The PBAC recommended listing on a cost-minimisation basis to ibrutinib, with equivalent treatment duration and inclusion in the existing Risk Sharing Arrangement for ibrutinib and venetoclax.</p> <p>The PBAC considered that acalabrutinib may provide, for some patients, a different toxicity profile compared to ibrutinib; however, due to the uncertainty of the data presented, did not accept the claim of superior safety and therefore advised that the cost of acalabrutinib would be the same as ibrutinib, and would exclude any cost-offsets for acalabrutinib.</p> <p>The PBAC noted that advice from the Medical Services Advisory Committee was still pending to include acalabrutinib on the existing MBS Item 73343 for the purpose of assessing PBS eligibility for acalabrutinib treatment.</p>
<p>ADALIMUMAB</p> <p>Injection 40 mg in 0.8 mL pre-filled syringe, 2</p> <p>Injection 40 mg in 0.8 mL pre-filled pen, 2</p> <p>Injection 40 mg in 0.8 mL pre-filled syringe, 6</p> <p>Injection 40 mg in 0.8 mL pre-filled pen, 6</p> <p>Hyrimoz®</p> <p>Sandoz Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Crohn disease</p> <p>Ulcerative colitis</p> <p>Juvenile idiopathic arthritis</p> <p>Fistulising Crohn disease</p> <p>Rheumatoid arthritis</p> <p>Psoriatic arthritis</p> <p>Ankylosing spondylitis</p> <p>Chronic plaque psoriasis</p> <p>Hidradenitis suppurativa</p>	<p>To request an Authority Required listing of a biosimilar adalimumab under the same conditions as the reference biologic.</p>	<p>The PBAC recommended the listing of the biosimilar brand of adalimumab, Hyrimoz®, for the same indications as the reference brand Humira® except for certain paediatric indications due to the absence of a 20 mg/0.4 mL injection presentation of Hyrimoz. The PBAC advised that, under Section 101(4AACD) of the <i>National Health Act, 1953</i>, in the Schedule of Pharmaceutical Benefits, Hyrimoz, Amgevita®, Hadlima® and Humira pre-filled syringes should be treated as equivalent ('a' flagged) to each other and Hyrimoz, Amgevita, Hadlima and Humira pre-filled pens should be treated equivalent ('a' flagged) to each other, for respective PBS-listed indications.</p> <p>The PBAC advised that the biosimilar uptake drivers should be applied to Hyrimoz, consistent with previous recommendations regarding the application of the drivers to other biosimilar brands of adalimumab.</p>

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<p>ALIROCUMAB</p> <p>Injection 75 mg in 1 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen</p> <p>Praluent®</p> <p>Sanofi-aventis Australia Pty Ltd</p> <p>Change to recommended listing (Minor Submission)</p>	<p>Hypercholesterolaemia</p>	<p>Resubmission to request an Authority Required listing for the treatment of hypercholesterolaemia in patients with atherosclerotic cardiovascular disease and additional high-risk factors.</p>	<p>The PBAC recommended the listing of alirocumab for the treatment of non-familial hypercholesterolaemia in patients with atherosclerotic cardiovascular disease and additional high-risk factors. The PBAC considered the issues raised at the March 2019 meeting regarding the proposed restriction, comparator, estimated cost-effectiveness, and financial implications were adequately addressed in the resubmission and recommended listing on a cost-minimisation basis compared with evolocumab. The PBAC advised that alirocumab should be included within the Risk Sharing Arrangement for evolocumab for the same indication.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</p> <p>Sachets containing oral powder 27.8 g, 30</p> <p>PKU Lophlex®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor submission)</p>	<p>Phenylketonuria (PKU)</p>	<p>To request a formulation change to PKU Lophlex for the dietary management of patients with PKU.</p>	<p>The PBAC recommended continuing the Restricted Benefit listing of PKU Lophlex®, for the dietary management of PKU following its reformulation. The PBAC also recommended amending the listing to reflect the change in sachet size from 27.8 g to 28 g to reflect the amended dose size.</p>

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<p>AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS</p> <p>Oral powder 400 g</p> <p>Neocate LCP®</p> <p>AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS</p> <p>Oral powder 400 g</p> <p>Neocate Syneo®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor submission)</p>	<p>Cow's milk allergy, multiple food intolerance and other medical conditions where an amino acid-based formula is recommended</p>	<p>To request a formulation change to Neocate LCP® and Neocate Syneo® for the dietary management of patients with Cow's milk allergy, multiple food intolerance and other medical conditions where an amino acid-based formula is recommended.</p>	<p>The PBAC recommended continuing the Restricted Benefit listing of Neocate LCP® and Neocate Syneo® for the dietary management of cow's milk allergy and multiple food allergies following their reformulation.</p>

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<p>APOMORPHINE</p> <p>Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL,</p> <p>Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen</p> <p>Apomine solution for infusion®; Apomine Intermittent®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Parkinson disease</p>	<p>To request General Schedule, Authority Required (STREAMLINED) listings of apomorphine for the continuing treatment of Parkinson Disease for patients who meet certain conditions, following initiation with the current Section 100 (Highly Specialised Drugs Program) listings.</p>	<p>The PBAC recommended expanding the listing of apomorphine 100 mg in 20 mL injection and 30 mg in 3 mL injection to include a listing on the General Schedule for patients requiring maintenance treatment of Parkinson Disease. The PBAC was satisfied that these changes would provide better access to apomorphine for patients in the maintenance phase of treatment.</p>
<p>ATEZOLIZUMAB</p> <p>Solution concentrate for I.V. infusion 840 mg in 14 mL</p> <p>Tecentriq®</p> <p>Roche Products Pty Ltd</p> <p>Change to recommended listing (Minor Submission)</p>	<p>Small cell lung cancer (SCLC)</p>	<p>To request listing of an additional vial size for the treatment of patients with extensive stage SCLC and to amend the recommended dosing regimens of atezolizumab for SCLC to allow clinician choice of either 1,200 mg every 3 weeks (Q3W) or 1,680 mg every 4 weeks (Q4W) dosing.</p>	<p>The PBAC recommended extending its November 2019 recommendation for the 840 mg in 14 mL injection of atezolizumab and the addition of the 1680 mg Q4W flat dosing regimen to include the treatment of previously untreated patients with extensive stage SCLC where atezolizumab monotherapy is used for continuing treatment.</p> <p>The PBAC considered that the effectiveness and safety of the 1680 mg Q4W dosing regimen is likely comparable to that of the 1200 mg Q3W dosing regimen for extensive stage SCLC.</p>

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<p>BENRALIZUMAB</p> <p>Injection 30 mg in 1 mL pre-filled pen</p> <p>Fasenra Pen®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Eosinophilic asthma</p>	<p>To request listing of an autoinjector presentation of benralizumab under the same conditions as the current pre-filled syringe.</p>	<p>The PBAC recommended the listing of a new form of benralizumab (pre-filled pen/auto-injector) for the treatment of uncontrolled severe eosinophilic asthma, on a cost-minimisation basis and under the same conditions as the current listing for benralizumab pre-filled syringe.</p>
<p>DUPIUMAB</p> <p>Injection 300 mg in 2 mL single use pre-filled syringe</p> <p>Dupixent®</p> <p>Sanofi-aventis Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Atopic dermatitis</p>	<p>Resubmission to request an Authority Required listing for the treatment of patients with chronic, moderate to severe, atopic dermatitis who have had an inadequate response to topical therapies.</p>	<p>The PBAC recommended the listing of dupilumab for the treatment of patients aged 12 years and older with severe atopic dermatitis who are inadequately controlled on topical therapies. The PBAC has previously acknowledged the significant reduction in the extent of disease and improved patient quality of life with dupilumab over standard of care in a therapeutic area of high clinical need. The PBAC considered that the proposed measures of disease assessment were adequately addressed in the resubmission. The PBAC considered that the incremental cost effectiveness ratio was likely underestimated in the resubmission and that this could be addressed with a reduced effective price. The PBAC considered that the potential for use of dupilumab outside the proposed restriction could be managed through a Risk Sharing Arrangement.</p>
<p>ENTRECTINIB</p> <p>Capsule 200 mg</p> <p>Rozlytrek®</p> <p>Roche Products Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request an Authority Required listing for the treatment of patients with locally advanced or metastatic c-ros proto-oncogene 1 (ROS1)-positive NSCLC.</p>	<p>The PBAC recommended the listing of entrectinib as monotherapy for the treatment of patients with locally advanced (Stage IIIB) or metastatic (Stage IV) ROS1-positive non-squamous or not otherwise specified (NOS) NSCLC.</p> <p>The PBAC recommended listing on a cost-minimisation basis compared with crizotinib. The PBAC considered that the listing of entrectinib may address an unmet clinical need for an alternative treatment option with a different safety profile compared to crizotinib.</p>

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<p>FLUOCINOLONE ACETONIDE</p> <p>Intravitreal injection 190 micrograms</p> <p>Iluvien®</p> <p>Specialised Therapeutics Pharma Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Diabetic macular oedema</p>	<p>To request an Authority Required listing for the treatment of patients with diabetic macular oedema who have had an inadequate response to corticosteroids.</p>	<p>The PBAC recommended the listing of fluocinolone acetonide intravitreal injection for the treatment of diabetic macular oedema in patients who are unsuitable for, contraindicated to, or have failed treatment with vascular endothelial growth factor inhibitors.</p> <p>The PBAC recommended listing on a cost-minimisation basis compared with dexamethasone implant. The PBAC advised the equi-effective doses should be 1.3 administrations of fluocinolone acetonide and 4.11 administrations of dexamethasone over 36 months.</p>
<p>FREMANEZUMAB</p> <p>Injection 225 mg in 1.5 mL pre-filled syringe</p> <p>Ajovy®</p> <p>Teva Pharma Australia Pty Ltd</p> <p>New listing (Other)</p>	<p>Chronic migraine</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the prophylactic treatment of adult patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications.</p>	<p>The PBAC recommended the listing of fremanezumab for the treatment of chronic migraine in patients who have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications. The PBAC considered fremanezumab was an alternative treatment to botulinum toxin type A (Botox®) for patients with chronic migraine and provided a similar reduction in migraine headache days.</p> <p>The PBAC considered the cost minimisation analysis should be based on equi-effective doses of 225 mg fremanezumab every month and 164U of Botox every 12 weeks over 2 years of treatment. Additionally, the PBAC considered it would be appropriate for the use, and associated expenditure, of fremanezumab to be restricted to the same high need patient population as for Botox.</p>

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<p>LISDEXAMFETAMINE</p> <p>Capsule containing lisdexamfetamine dimesilate 20mg</p> <p>Capsule containing lisdexamfetamine dimesilate 30mg</p> <p>Capsule containing lisdexamfetamine dimesilate 40mg</p> <p>Capsule containing lisdexamfetamine dimesilate 50mg</p> <p>Capsule containing lisdexamfetamine dimesilate 60mg</p> <p>Capsule containing lisdexamfetamine dimesilate 70mg</p> <p>Vyvanse®</p> <p>Shire Australia Pty Limited</p> <p>Change to listing (Minor Submission)</p>	<p>Attention deficit hyperactivity disorder (ADHD)</p>	<p>To request removal of the age of diagnosis criterion from the Authority Required listings of lisdexamfetamine for the treatment of ADHD.</p>	<p>The PBAC recommended extending the listing of lisdexamfetamine for the treatment of ADHD to include patients who are diagnosed after the age of 18. The PBAC recognised the clinical need for effective treatments for this cohort of patients and considered it appropriate for there to be equitable access to treatment regardless of age of diagnosis. However, the PBAC considered the supporting evidence for superiority of lisdexamfetamine compared to immediate release dexamfetamine in adults was limited and therefore did not recommend the requested price premium. The PBAC considered that uncertainty surrounding the potential uptake in the adult population could be managed by subsidisation caps through a Risk Sharing Arrangement.</p>

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<p>MEPOLIZUMAB</p> <p>Injection 100 mg in 1 mL pre-filled pen Injection 100 mg in 1 mL pre-filled syringe</p> <p>Nucala®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>New Listing (Minor Submission)</p>	<p>Eosinophilic asthma</p>	<p>To request listing of pre-filled syringe and pre-filled pen presentations of mepolizumab under the same conditions as mepolizumab powder for injection 100 mg.</p>	<p>The PBAC recommended the listing of new forms of mepolizumab (pre-filled pen and pre-filled syringe) for the treatment of uncontrolled severe eosinophilic asthma, on a cost-minimisation basis and under the same conditions as the current listing for mepolizumab powder for injection 100 mg.</p>
<p>MESALAZINE</p> <p>Suppository 1 g Sachet containing granules, 1 g per sachet</p> <p>Pentasa®</p> <p>Ferring Pharmaceuticals Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Ulcerative proctitis Ulcerative colitis Crohn disease</p>	<p>To request a change to the maximum quantity for the 1 g suppository (from 30 to 28 units) and 1 g sachet containing granules (from 120 to 100 sachets) forms of the Pentasa® brand of mesalazine, in line with changes to the pack sizes.</p>	<p>The PBAC recommended the change in maximum quantity for mesalazine suppositories and modified release granules based on the change to pack sizes. The PBAC noted that price for both the suppositories and the modified release granules were adjusted proportionately to the change in pack size, and would not increase the cost to the PBS.</p>

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<p>METHYLPHENIDATE</p> <p>Capsule containing methylphenidate hydrochloride 60 mg (modified release)</p> <p>Ritalin LA®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>New listing (Minor Submission)</p>	<p>Attention deficit hyperactivity disorder (ADHD)</p>	<p>To request an Authority Required listing of a new strength of modified release methylphenidate.</p>	<p>The PBAC recommended listing methylphenidate modified release 60 mg capsule (Ritalin LA® 60 mg), under the same conditions as the currently listed Ritalin LA strengths (10 mg, 20 mg, 30 mg and 40 mg). The PBAC acknowledged that listing a higher strength of Ritalin LA may benefit ADHD patients who are prescribed higher doses of methylphenidate, including older children and adults.</p>
<p>MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE</p> <p>Oral powder 225 g</p> <p>Carbohydrate Free Mixture®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Ketogenic diet</p>	<p>To request a formulation change to Carbohydrate Free Mixture® for the dietary management of patients requiring a ketogenic diet.</p>	<p>The PBAC recommended continuing the listing Carbohydrate Free Mixture®, for infants and children with multiple monosaccharide intolerance or requiring a ketogenic diet, on the PBS following its reformulation.</p>
<p>OLAPARIB</p> <p>Capsule 50 mg Tablet 100 mg Tablet 150 mg</p> <p>Lynparza®</p> <p>AstraZeneca Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>High grade serous ovarian cancer High grade serous fallopian tube cancer High grade serous primary peritoneal cancer</p>	<p>Resubmission to request the current Authority Required (STREAMLINED) listings for olaparib be amended to include somatic BRCA 1/2 (BReast CAncer gene) mutation testing as an option to determine eligibility for treatment.</p>	<p>The PBAC recommended that the existing olaparib listing for the treatment of platinum-sensitive relapsed ovarian, fallopian tube and primary peritoneal cancer in patients with germline BRCA1/2 mutations be amended to also include patients with somatic BRCA1/2 mutations. The PBAC considered that it was reasonable to assume the cost effectiveness of olaparib in patients with somatic BRCA1 or BRCA2 mutation would be similar to that in patients with germline BRCA1 or BRCA2 mutation, as previously accepted by the PBAC. This followed MSAC's support at its November 2019 meeting for MBS listing of somatic BRCA testing to help identify additional patients who may be suitable for treatment with olaparib.</p>

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<p>PEGFILGRASTIM</p> <p>Injection 6 mg in 0.6 mL single use pre-filled syringe</p> <p>Pelgraz[®]</p> <p>Accord Healthcare Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Chemotherapy-induced neutropenia</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a biosimilar pegfilgrastim under the same conditions as the reference biologic.</p>	<p>The PBAC recommended the listing of the biosimilar brand of pegfilgrastim, Pelgraz[®], on the Section 100 (Highly Specialised Drugs Program) for all indications for which the reference brand, Neulasta[®] is currently PBS-listed. The PBAC advised that, under Section 101(4AACD) of the <i>National Health Act, 1953</i>, in the Schedule of Pharmaceutical Benefits, Pelgraz should be treated as equivalent ('a' flagged) with the other brands of pegfilgrastim.</p> <p>The PBAC recommended the addition of an administrative note to encourage the uptake of biosimilar prescribing for treatment naïve patients, in accordance with the Australian Government's Biosimilar Uptake Driver policy.</p>
<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda[®]</p> <p>Merck, Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Melanoma</p>	<p>To request an extension of the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable Stage III or IV malignant melanoma to allow use as a first-line therapy in patients who are BRAF V600 mutation positive.</p>	<p>The PBAC recommended the extension of the listing for pembrolizumab to allow its use as a first-line therapy in the treatment of BRAF V600 mutant Stage III or Stage IV unresectable or metastatic melanoma. The PBAC considered that pembrolizumab would be cost-effective in this population if it was cost-minimised to nivolumab, which was recommended for the same indication in November 2019. In addition, the PBAC recommended that the extended listing of pembrolizumab be included in the current Risk Sharing Arrangement for programmed cell death-1 inhibitors in the treatment of melanoma.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck, Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Melanoma Non-small cell lung cancer (NSCLC)</p>	<p>To request amending the recommended dosing regimens of pembrolizumab for melanoma or NSCLC to allow clinician choice of either 200 mg every 3 weeks (Q3W) or 400 mg every 6 weeks (Q6W) dosing.</p>	<p>The PBAC recommended the addition of the 400 mg Q6W flat dosing regimen to the existing 200 mg Q3W flat dosing regimen for all existing and recommended pembrolizumab PBS listings for melanoma and NSCLC indications where pembrolizumab monotherapy is used. The PBAC noted that no clinical data comparing the 400 mg Q6W dosing regimen to the 200 mg Q3W dosing regimen was provided. However, based on the pharmacokinetic modelling data evaluated by the TGA, the PBAC considered that the effectiveness and safety of the two flat dosing regimens would likely be comparable.</p> <p>The PBAC considered that although the utilisation of the 400 mg Q6W dosing regimen was uncertain, there would be some cost-savings to the Government associated with the addition of this dosing regimen due to the reduced administration and dispensing costs from the fewer scripts dispensed for the Q6W dosing regimen compared to the Q3W dosing regimen.</p>
<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck, Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Primary mediastinal B-cell lymphoma (PMBCL)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with relapsed or refractory (R/R) PMBCL who meet certain conditions.</p>	<p>The PBAC recommended the listing of pembrolizumab for the treatment of R/R PMBCL. The PBAC recognised the high clinical need for treatment options for this rare disease and was satisfied that pembrolizumab showed effectiveness in the R/R PMBCL setting where patients may have no other potentially curable options available.</p> <p>The PBAC considered that the cost-effectiveness of pembrolizumab was uncertain but could be managed by a price reduction and subsidisation caps through a Risk Sharing Arrangement.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Melanoma</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage IIIB-D malignant melanoma.</p>	<p>The PBAC recommended the listing of pembrolizumab as adjuvant treatment for patients who have had completely surgically resected Stage IIIB, IIIC or IIID malignant melanoma. The PBAC had previously deferred making a recommendation as it considered it appropriate for pembrolizumab to be listed on a cost-minimisation basis versus nivolumab. The PBAC noted that the listing of nivolumab had since been agreed. The PBAC considered that the uncertainty surrounding uptake in the adjuvant setting and changes to use in the unresectable or metastatic setting could be managed by subsidisation caps through a Risk Sharing Arrangement and recommended that pembrolizumab join the arrangement agreed for nivolumab, which reflected likely use across both settings.</p>
<p>ROMOSOZUMAB</p> <p>Injection 105 mg in 1.17 mL single use pre-filled syringe</p> <p>Evenity®</p> <p>Amgen Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Osteoporosis</p>	<p>Resubmission to request an Authority Required listing for the treatment of patients with severe osteoporosis.</p>	<p>The PBAC recommended the listing of romosozumab for the treatment of severe osteoporosis in patients who have experienced a prior fracture while on anti-resorptive therapy. The PBAC considered there is a clinical need for additional treatment options for severe osteoporosis in the later-line setting. The PBAC considered that the revised cost-minimisation analysis presented in the resubmission partially addressed previous concerns regarding the cost-effectiveness of romosozumab.</p> <p>The PBAC considered the equi-effective doses were: 10.8 scripts of romosozumab 210 mg once monthly over 365 days of therapy and 14.22 scripts of teriparatide 20 mcg once daily over 504 days of therapy. The PBAC considered that the remaining uncertainties could be managed by subsidisation caps through a Risk Sharing Arrangement.</p>

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<p>SEMAGLUTIDE</p> <p>Injection 2 mg in 1.5 mL pre-filled syringe Injection 4 mg in 3 mL pre-filled syringe</p> <p>Ozempic®</p> <p>Novo Nordisk Pharmaceuticals Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Type 2 diabetes mellitus (T2DM)</p>	<p>Resubmission to request the PBAC review its advice on the therapeutic relativities and equi-effective doses of semaglutide and dulaglutide as part its November 2019 recommendation for semaglutide for use in combination with metformin and/or a sulfonylurea for the treatment of patients with T2DM.</p>	<p>The PBAC recommended that semaglutide 0.5 mg should be considered equi-effective to dulaglutide 1.5 mg for treatment of patients with T2DM who have inadequate glycaemic control, as dual therapy in combination with metformin or a sulfonylurea where either of these is contraindicated or not tolerated; or triple therapy in combination with metformin and a sulfonylurea.</p>
<p>STIRIPENTOL</p> <p>Capsule 250 mg Capsule 500mg Powder for oral suspension 250 mg Powder for oral suspension 500 mg</p> <p>Diacomit®</p> <p>Emerge Health Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Severe myoclonic epilepsy in infancy (SMEI) (also known as Dravet syndrome)</p>	<p>To request an Authority Required (STREAMLINED) listing for adjunctive treatment of patients with generalised clonic and tonic-clonic seizures associated with SMEI who meet certain conditions.</p>	<p>The PBAC recommended the listing of stiripentol as adjuvant treatment of patients with generalised clonic and tonic-clonic seizures associated with SMEI who are not adequately controlled by prior lines of therapy.</p> <p>The PBAC noted the limitations with the clinical evidence and economic model given the variable and individualised nature of current standard care in SMEI, but considered there is a high unmet clinical need for effective treatment options in this therapeutic area, noting that the patient population is small.</p>

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<p>TOCILIZUMAB</p> <p>Injection 162 mg in 0.9 mL single use prefilled pen Injection 162 mg in 0.9 mL single use prefilled syringe</p> <p>Actemra®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Systemic juvenile idiopathic arthritis (JIA)</p>	<p>To request an extension of the current Authority Required listing of subcutaneous tocilizumab to include the treatment of patients with systemic JIA.</p>	<p>The PBAC recommended the listing of subcutaneous (SC) presentations of tocilizumab for the treatment of systemic juvenile idiopathic arthritis on a cost-minimisation basis to intravenous (IV) tocilizumab. The PBAC considered that tocilizumab SC was likely to be equivalent in efficacy and safety to tocilizumab IV. The equi-effective doses were:</p> <ul style="list-style-type: none"> • for patients <30 kg tocilizumab SC 162 mg every two weeks and tocilizumab IV 12 mg/kg every two weeks; • for patients > 30 kg tocilizumab SC 162 mg every week and tocilizumab IV 8 mg/kg every two weeks.
<p>TRIGLYCERIDES MEDIUM CHAIN FORMULA</p> <p>Oral powder 400 g</p> <p>Lipistart®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Dietary management of conditions requiring a source of medium chain triglycerides</p>	<p>To request a formulation change to Lipistart® for the dietary management of patients with fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders.</p>	<p>The PBAC recommended continuing the listing of the Lipistart® on the PBS following its reformulation.</p>
<p>TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER</p> <p>Oral powder 400 g</p> <p>Duocal®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Proven inborn errors of protein metabolism</p>	<p>To request a formulation change to Duocal® for the dietary management of patients with proven inborn errors of metabolism.</p>	<p>The PBAC recommended continuing the listing of Duocal® on the PBS following its reformulation.</p>

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<p>WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE</p> <p>Oral powder 400 g, 6 Sachets containing oral powder 100 g, 10</p> <p>Renastart®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chronic kidney disease (CKD)</p>	<p>To request a formulation change to Renastart® for the dietary management of eligible paediatric patients with CKD.</p>	<p>The PBAC recommended continuing the listing of Renastart® for the dietary management of CKD in infants and young children on the PBS following its reformulation.</p>