

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ADALIMUMAB</p> <p>Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL single dose autoinjector</p> <p>Hadlima®</p> <p>Merck, Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Severe active rheumatoid arthritis Severe psoriatic arthritis Ankylosing spondylitis Severe chronic plaque psoriasis Juvenile idiopathic arthritis Severe Crohn's disease Refractory fistulising Crohn's disease Moderate to severe hidradenitis suppurativa</p>	<p>To request an extension to the currently approved PBS listing of Hadlima® to include all indications for which Humira® is currently PBS listed.</p>	<p>The PBAC recommended extending the recommendation for the Hadlima® brand of adalimumab (as a biosimilar of the Humira® reference biologic) for the remaining indications for which Humira® is PBS listed. The PBAC advised that the pre-filled syringe forms of the four brands of adalimumab should be treated as equivalent to each other, and that the pre-filled pen forms of the four brands should be treated equivalent to each other for the purposes of substitution (i.e. 'a' flagged) to each other.</p> <p>The PBAC advised that biosimilar uptake drivers should apply to the expanded recommendation for Hadlima®, consistent with previous recommendations for other biosimilar brands of adalimumab.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE</p> <p>Sachets containing oral powder 28 g, 30</p> <p>HCU Lophlex®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Pyridoxine non-responsive homocystinuria (HCU)</p>	<p>To request PBS listing of HCU Lophlex® for the dietary management of HCU.</p>	<p>The PBAC recommended the listing of HCU Lophlex® for the management of pyridoxine non-responsive HCU on a cost-minimisation basis per gram of protein with the nominated comparators.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE</p> <p>Sachets containing oral powder 28 g, 30</p> <p>TYR Lophlex®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Tyrosinaemia</p>	<p>To request PBS listing of TYR Lophlex® for the dietary management of tyrosinaemia.</p>	<p>The PBAC recommended the listing of TYR Lophlex® for the management of tyrosinaemia on a cost-minimisation basis per gram of protein with the nominated comparators.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE</p> <p>Sachets containing oral powder 28 g, 30</p> <p>MSUD Lophlex®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Maple syrup urine disease (MSUD)</p>	<p>To request PBS listing of MSUD Lophlex® for the dietary management of MSUD.</p>	<p>The PBAC recommended the listing of MSUD Lophlex® for the management of MSUD on a cost-minimisation basis per gram of protein with the nominated comparators.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , THREONINE AND VALINE AND LOW IN ISOLEUCINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE</p> <p>Oral powder 400 g</p> <p>PKU Anamix Infant® TYR Anamix Infant® GA1 Anamix Infant® MMA/PA Anamix Infant® HCU Anamix Infant® MSUD Anamix Infant®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Phenylketonuria (PKU) Tyrosinaemia Glutaric aciduria type 1 (GA1) Methylmalonic acidaemia (MMA) and Propionic acidaemia (PA) Proven pyridoxine non-responsive homocystinuria (HCU) Proven maple syrup urine disease (MSUD)</p>	<p>To request a change to the formulation of Anamix Infant products.</p>	<p>The PBAC recommended continuing the listings of:</p> <ul style="list-style-type: none"> • PKU Anamix Infant® for the dietary management of PKU; • TYR Anamix Infant® for the dietary management of Tyrosinaemia; • GA1 Anamix Infant® for the dietary management of proven GA1; • MMA/PA Anamix Infant® for the dietary management of proven MMA and PA; • HCU Anamix Infant® for the dietary management of proven pyridoxine non-responsive HCU; and • MSUD Anamix Infant® for the dietary management of proven MSUD, following their reformulation due to changes in European compositional standards.

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>APREMILAST</p> <p>Tablet 30 mg Pack containing 4 tablets of 10 mg, 4 tablets of 20 mg and 19 tablets of 30 mg Otezla®</p> <p>Amgen Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Plaque psoriasis</p>	<p>Resubmission to request the Authority Required (STREAMLINED) listing of apremilast for the treatment of plaque psoriasis.</p>	<p>The PBAC recommended the listing of apremilast for the treatment of severe chronic plaque psoriasis in patients who have failed treatment with or who are contraindicated or intolerant to methotrexate. The PBAC recommended listing on a cost-minimisation basis with cyclosporin after accounting for differential adverse event and patient monitoring costs. In making this recommendation, the PBAC accepted that the resubmission had adequately addressed concerns raised in previous considerations and had appropriately proposed a price and Risk Sharing Arrangement consistent with Committee's November 2017 advice.</p>
<p>ATEZOLIZUMAB + BEVACIZUMAB</p> <p>Atezolizumab: Solution concentrate for I.V. infusion 1200 mg in 20 mL, Solution concentrate for I.V. infusion 840 mg in 14 mL</p> <p>Tecentriq®</p> <p>Bevacizumab: Solution for I.V. infusion 100 mg in 4 mL, Solution for I.V. infusion 400 mg in 16 mL</p> <p>Avastin®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Hepatocellular carcinoma (HCC)</p>	<p>To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for the treatment of patients with unresectable locally advanced or metastatic Barcelona Clinic Liver Cancer (BCLC) Stage B or Stage C HCC who have not received prior systemic therapy.</p>	<p>The PBAC recommended the listing of atezolizumab in combination with bevacizumab (Atezo+Bev) for the treatment of patients with advanced unresectable BCLC Stage B or Stage C HCC who have not received prior systemic treatment. The PBAC considered there was a high clinical need in this patient population and recognised the substantial clinical benefit provided by Atezo+Bev, despite the immaturity of the overall survival data. The PBAC considered that the cost-effectiveness of Atezo+Bev would be acceptable at the price proposed in the submission, with an appropriate Risk Sharing Arrangement to manage the risk of use outside the restriction.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>BECLOMETASONE DIPROPIONATE + FORMOTEROL FUMARATE DIHYDRATE</p> <p>Powder for oral inhalation in breath actuated device containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses</p> <p>Fostair®</p> <p>Emerge Health Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Asthma</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with asthma.</p>	<p>The PBAC recommended the listing of the fixed dose combination (FDC) of beclometasone (BEC) with formoterol (FOR) for the maintenance treatment of asthma. The PBAC recommended listing on a cost-minimisation basis compared with the least costly combination of an inhaled corticosteroid with a long-acting beta2 agonist FDC or combination of the individual components (BEC + FOR) at comparable doses.</p> <p>The PBAC did not recommend the listing of BEC/FOR for asthma maintenance and reliever therapy due to concerns the data presented were not adequate to support a listing for this indication and the potential for quality use of medicine issues.</p>
<p>BEVACIZUMAB</p> <p>Solution for I.V. infusion 100 mg in 4 mL Solution for I.V infusion 400 mg in 16 mL</p> <p>Zirabev®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Advanced International Federation of Gynecology and Obstetrics Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer Advanced carcinoma of cervix Relapsed or recurrent glioblastoma Stage IV (metastatic) non-small cell lung cancer Metastatic colorectal cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new biosimilar bevacizumab under the same conditions as the reference biologic</p>	<p>The PBAC recommended the listing of bevacizumab (Zirabev®) 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 authority for initial treatment and telephone authority for continuing treatment.</p> <p>The PBAC noted that Efficient Funding of Chemotherapy medicines are governed by the <i>National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011</i>, and that Section 33(2) allows substitution of brands under the same item code.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>BIMATOPROST</p> <p>300 micrograms per mL, 3 mL</p> <p>Vizo-PF Bimatoprost®</p> <p>AFT Pharmaceuticals Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Reduction of elevated intraocular pressure or open angle glaucoma, as first-line therapy or monotherapy or as adjunctive therapy to topical beta-blockers.</p>	<p>To request the unrestricted PBS listing for Vizo-PF Bimatoprost® for the reduction of elevated intraocular pressure, or open angle glaucoma, as first-line therapy or monotherapy or as adjunctive therapy to topical beta-blockers.</p>	<p>The PBAC recommended the listing of Vizo-PF Bimatoprost® in a preservative-free multi-dose bottle for the reduction of elevated intraocular pressure, or open angle glaucoma, as first-line therapy or monotherapy or as adjunctive therapy to topical beta-blockers. The PBAC recommended listing on a cost-minimisation basis compared with the lowest priced alternative agent.</p>
<p>CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS</p> <p>Oral powder 400 g</p> <p>Energivit®</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 of Energivit® for the dietary management of proven inborn errors of protein metabolism.</p>	<p>The PBAC recommended continuing the listing of Energivit® on the PBS following its reformulation.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>CARFILZOMIB</p> <p>Powder for injection 10 mg Powder for injection 30 mg Powder for injection 60 mg</p> <p>Kyprolis®</p> <p>Amgen Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Multiple myeloma (MM)</p>	<p>To request:</p> <ul style="list-style-type: none"> • A change to authority level from telephone authority to streamlined authority for both initial and continuing treatment; • An amendment to the current dosing regimen of carfilzomib to allow a weekly dosing regimen of 70 mg/m² carfilzomib and dexamethasone; • An increase in the maximum amount from 120 mg to 160 mg to allow for the weekly dosing of 70 mg/m² carfilzomib and dexamethasone. 	<p>The PBAC recommended the addition of the 70 mg/m² once weekly (70 QW) dosing regimen to the existing 56 mg/m² twice weekly (56 BIW) dosing regimen where carfilzomib is used in combination with dexamethasone (Cd) for the treatment of patients with relapsed or refractory (RR) MM. The PBAC considered that Cd70 QW is likely to be comparable in effectiveness and safety to Cd56 BIW for RRMM.</p> <p>The PBAC recommended a new listing of carfilzomib with a maximum dose of 160 mg to allow for once weekly dosing. The PBAC also considered it would be appropriate to lower the restriction authority type from Authority Required (Telephone) to Authority Required (STREAMLINED) for all carfilzomib listings in both initial and continuing treatment of RRMM to help improve patient access to MM treatment.</p> <p>The PBAC considered the cost-minimisation analysis should be based on the equi-effective doses (cumulative) of 4969 mg for Cd70 QW and 7278 mg for Cd56 BIW. The PBAC considered that uncertainties around uptake being higher than estimated in the submission could be managed by the current Risk Sharing Arrangement for carfilzomib.</p>
<p>CATIONIC OPHTHALMIC EMULSION, PRESERVATIVE FREE</p> <p>Eye drops containing heavy mineral oil 0.5% and light mineral oil 0.5%, 10 mL</p> <p>Cationorm®</p> <p>Seqirus (Australia) Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Severe dry eye syndrome</p>	<p>To request an Authority Required (STREAMLINED) PBS listing for the treatment of severe dry eye syndrome.</p>	<p>The PBAC recommended the listing of Cationorm® for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops. The PBAC recommended listing on a cost-minimisation basis, at the lowest cost per treatment, compared with other PBS listed preservative-free, multi-dose ocular lubricants (Evolve® carmellose 0.5% and Evolve® hypromellose 0.3%).</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX</p> <p>Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units</p> <p>Dysport®</p> <p>Ipsen Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Focal spasticity of the upper limb</p>	<p>To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing to include the treatment of focal spasticity of the upper limb in patients with cerebral palsy aged 2 years or older.</p>	<p>The PBAC recommended the listing of Dysport® for the treatment of moderate to severe focal spasticity of the upper limb in patients with cerebral palsy. Although the indirect comparison between Dysport® and the nominated comparator, Botox®, had a number of issues including small patient numbers and heterogeneity, the PBAC was satisfied that Dysport® was non-inferior to Botox® in terms of comparative efficacy and safety. Based on the maximum dispensed quantity of Dysport® for upper limb spasticity, the PBAC considered that the equi-effective doses of Dysport® and Botox® were: 2.5 U Dysport® = 1.0 U Botox®.</p>
<p>DARATUMUMAB</p> <p>100 mg/5 mL injection, 5 mL vial 400 mg/20 mL injection, 20 mL vial</p> <p>Darzalex®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Multiple myeloma (MM)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of second-line MM in combination with bortezomib and dexamethasone.</p>	<p>The PBAC recommended the listing of daratumumab, for use in combination with bortezomib and dexamethasone (DBd), as a second-line treatment for patients with MM, on the basis that it should be available only under special arrangements under the Section 100 Efficient Funding of Chemotherapy program. The PBAC noted that daratumumab monotherapy would be provided by the sponsor to all eligible relapsed and/or refractory MM patients who have no other PBS-funded treatment options on a compassionate basis.</p> <p>The PBAC noted that a revised economic evaluation was presented which incorporated the Committee's previous recommendations. The PBAC considered daratumumab would be cost-effective if the incremental cost-effectiveness ratio was reduced to be in the range of \$45,000 to \$75,000 per quality adjusted life year.</p> <p>The PBAC considered the financial impact estimates were revised appropriately in the minor resubmission, and noted that these estimates formed the basis of the proposed Risk Sharing Arrangement.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>DOLUTEGRAVIR + LAMIVUDINE</p> <p>Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg</p> <p>Dovato®</p> <p>ViiV Healthcare Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Human immunodeficiency virus (HIV) infection</p>	<p>To request an extension of the current Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing to include the treatment of HIV infection in antiretroviral therapy experienced patients.</p>	<p>The PBAC recommended amending the listing of dolutegravir with lamivudine (DTG/3TC) to permit use in patients who are treatment-experienced with other anti-retroviral regimens, at the same price as the component drugs dolutegravir and lamivudine, taken concomitantly.</p> <p>The recommendation was based on the PBAC’s assessment of the 48-week data from the TANGO study, which evaluated the efficacy and safety of DTG/3TC in patients who switched from a tenofovir-based regimen and supported a conclusion that DTG/3TC is likely non-inferior in effectiveness and safety compared to alternative three-drug regimens.</p>
<p>DULAGLUTIDE</p> <p>Injection 1.5 mg in 0.5 mL single dose pre-filled pen</p> <p>Trulicity®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Type 2 Diabetes Mellitus (T2DM)</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for use in combination with insulin and metformin for the treatment of patients with T2DM.</p>	<p>The PBAC recommended extending the existing listing of dulaglutide to include the treatment of T2DM in combination with insulin and metformin unless contraindicated or not tolerated. The PBAC recommended listing for dulaglutide 1.5 mg once weekly (QW) on a cost-minimisation basis compared with exenatide 10 mcg twice daily (BID).</p> <p>The PBAC considered that the QW dosing regimen of dulaglutide may improve health outcomes for some patients, particularly those with poor adherence, due to less frequent injections compared with exenatide BID. As such, the PBAC considered a small price advantage to be reasonable on the basis of potential health benefits from likely improved adherence in a small number of patient populations. However, the PBAC advised that the price advantage for dulaglutide QW, when used with insulin and metformin (unless contraindicated or not tolerated), should be no higher than that which currently applies to dulaglutide QW for use with metformin and/or a sulfonylurea.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ENOXAPARIN</p> <p>Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL syringe</p> <p>Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL syringe</p> <p>Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL syringe</p> <p>Enoxapo®</p> <p>Apotex Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Prevention and treatment of deep vein thrombosis; Haemodialysis</p>	<p>To request the Restricted Benefit listing of a biosimilar enoxaparin for the same indications as the originator brand Clethane Safety-Lock®.</p>	<p>The PBAC recommended the listing of the biosimilar brand of enoxaparin (Enoxapo®) on a cost-minimisation basis for the same indications and level of restrictions for which the reference product Clethane Safety-Lock® is currently PBS listed. The PBAC recommended listing for Enoxapo® 120 mg/0.8 mL and 150 mg/mL on a cost-minimisation basis compared with enoxaparin 100 mg/mL.</p> <p>The PBAC advised that, under Section 101(4AACD) of the <i>National Health Act 1953</i>, Enoxapo® should be treated as equivalent ('a' flagged) with the other brands of enoxaparin in the Schedule of Pharmaceutical Benefits.</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>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE)/ PALONOSETRON (AS HYDROCHLORIDE)</p> <p>Powder for Injection containing fosnetupitant 235 mg and palonosetron 250 mg</p> <p>Akynzeo IV®</p> <p>Mundipharma Pty Limited</p> <p>New listing (Minor Submission)</p>	<p>Nausea and vomiting</p>	<p>To request a General Schedule and Section 100 Efficient Funding of Chemotherapy Authority Required (STREAMLINED) listing of an IV form of fosnetupitant/palonosetron under the same conditions as the capsule form.</p>	<p>The PBAC recommended the listing of Akynzeo IV® under the same conditions as the currently PBS listed capsule form, netupitant 300 mg plus palonosetron 500 mcg capsule (Akynzeo®), and on a cost-minimisation basis to the lowest cost combination of a neurokinin-1 receptor antagonist with a 5-hydroxytryptamine (serotonin) receptor antagonist.</p>
<p>FULVESTRANT</p> <p>Injection 250 mg in 5 mL pre-filled syringe</p> <p>Faslodex®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Breast cancer</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with hormone receptor positive, human epidermal growth factor receptor-2 negative (HER2) advanced breast cancer.</p>	<p>The PBAC recommended the listing of fulvestrant for the treatment of patients with unresectable advanced or metastatic breast cancer. The PBAC was satisfied that first-line treatment with fulvestrant provides, for some patients, an improvement in efficacy over non-steroidal aromatase inhibitors. The PBAC also considered, on balance, that fulvestrant provides acceptable effectiveness and potentially increased safety and tolerability in subsequent lines of therapy.</p> <p>The PBAC considered that the magnitude of benefit for first-line treatment with fulvestrant was uncertain due to limitations in the trial data and its applicability to the PBS population. This resulted in uncertainty in the incremental cost-effectiveness ratio (ICER) presented, which the PBAC considered could be addressed through a price reduction to achieve an acceptable ICER. The PBAC considered that a reduction in price for subsequent line use was also appropriate, given the high level of uncertainty in the clinical evidence presented.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS</p> <p>Sachets containing oral powder 31 g, 30</p> <p>Tylactin Build 20®</p> <p>Cortex Health Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Tyrosinaemia</p>	<p>To request a Restricted Benefit listing for the dietary management of patients with tyrosinaemia.</p>	<p>The PBAC recommended the listing of a new glycomacropeptide formula, Tylactin Build 20®, for the dietary management of tyrosinaemia on a cost-minimisation basis to the lowest cost alternative on the PBS for the same condition, at an equivalent cost per gram of protein equivalent.</p>
<p>GUSELKUMAB</p> <p>Solution for injection 100 mg in 1 mL pen device</p> <p>Tremfya®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Severe chronic plaque psoriasis</p>	<p>To request the Authority Required (Written) PBS listing of a pre-filled pen presentation of guselkumab (Tremfya®) 100 mg under the same conditions as the existing pre-filled syringe presentation.</p>	<p>The PBAC recommended the listing of a new form of guselkumab (pre-filled pen) 100 mg under the same arrangements as the currently listed guselkumab pre-filled syringe 100 mg.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>INDACATEROL+ MOMETASONE</p> <p>Capsule containing powder for oral inhalation mometasone furoate 80 micrograms with indacaterol 150 micrograms (as acetate) (for use in Breezhaler®)</p> <p>Capsule containing powder for oral inhalation mometasone furoate 160 micrograms with indacaterol 150 micrograms (as acetate) (for use in Breezhaler®)</p> <p>Capsule containing powder for oral inhalation mometasone furoate 320 micrograms with indacaterol 150 micrograms (as acetate) (for use in Breezhaler®)</p> <p>Aectura Breezhaler®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Asthma</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of asthma.</p>	<p>The PBAC recommended the listing of the fixed dose combination (FDC) of mometasone furoate (MF) with indacaterol (IND) for the maintenance treatment of asthma. The PBAC recommended listing on a cost-minimisation basis compared with the least costly PBS listed inhaled corticosteroid with long-acting beta2 agonist FDC product at comparable doses for each MF/IND strength.</p>
<p>IXEKIZUMAB</p> <p>Injection 80 mg in 1 mL single dose pre-filled pen</p> <p>Taltz®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Ankylosing spondylitis</p>	<p>To request an extension to the current Authority Required listing to include the treatment of patients with active ankylosing spondylitis.</p>	<p>The PBAC recommended the listing of ixekizumab on a cost-minimisation basis to the least costly biological medicine for ankylosing spondylitis.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>MILK POWDER SYNTHETIC LOW CALCIUM</p> <p>Low calcium oral powder 400 g</p> <p>Locasol®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Hypercalcaemia</p>	<p>To request a formulation change of Locasol® for the dietary management of hypercalcaemia.</p>	<p>The PBAC recommended continuing the listing of Locasol® for the dietary management of hypercalcaemia for patients under the age of four years (inclusive), following its reformulation due to changes in European compositional standards.</p>
<p>NUSINERSEN</p> <p>Solution for injection 12 mg in 5 mL</p> <p>Spinraza®</p> <p>Biogen Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Spinal muscular atrophy (SMA)</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals) Authority Required listing for the treatment of patients with pre-symptomatic, infantile and childhood-onset SMA.</p>	<p>The PBAC recommended the addition of pre-symptomatic initiation to the current listing of nusinersen to include the pre-symptomatic initiation of treatment of patients genetically diagnosed with SMA, who have a Survival-of-Motor-Neuron 2 (SMN2) gene copy number of 1 or 2 (i.e. SMN2 copy number ≤2). The PBAC considered that pre-symptomatic initiation of treatment with nusinersen would provide an additional benefit for some patients compared with initiation upon development of symptoms. The PBAC acknowledged that the current requirement for symptoms to develop prior to accessing subsidised treatment could have a significant burden on the families of infants genetically diagnosed with SMA.</p> <p>The PBAC noted there was remaining uncertainty around the cost-effectiveness of pre-symptomatic initiation of treatment with nusinersen due to the uncertain magnitude of incremental benefit compared to symptomatic treatment. However, the PBAC was satisfied that extension of the current listing would be cost-effective if the conditions specified in the existing Risk Sharing Arrangement (RSA) were also applied to the extended listing.</p> <p>The PBAC advised that the extended listing should be included in the current RSA in place for nusinersen to manage this uncertainty.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>OLAPARIB</p> <p>Tablet 100 mg Tablet 150 mg</p> <p>Lynparza®</p> <p>AstraZeneca Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Ovarian, fallopian tube or primary peritoneal cancer</p>	<p>Resubmission to request an Authority Required listing for newly diagnosed advanced BRCA-mutated high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in response (complete or partial) to first-line platinum-based chemotherapy.</p>	<p>The PBAC recommended the listing for patients with newly diagnosed advanced BRCA-mutated high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in response (complete response or partial response) to 1L platinum-based chemotherapy. The PBAC recognised the clinical need for effective treatments for patients with ovarian cancer prior to disease relapse. The PBAC was satisfied that first-line maintenance with olaparib provides, for some patients, a significant delay in the time to progression and subsequent treatment. The PBAC considered olaparib would be cost-effective if the economic model was revised to address the uncertain gain in overall survival and the price for first-line olaparib reduced to bring the incremental cost-effectiveness ratio into an acceptable range.</p>
<p>OSIMERTINIB</p> <p>Tablet 40 mg Tablet 80 mg</p> <p>Tagrisso®</p> <p>AstraZeneca Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>Resubmission to request an Authority Required listing for the first-line treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic) epidermal growth factor receptor (EGFR) mutation positive NSCLC.</p>	<p>The PBAC recommended the listing of osimertinib for the first-line treatment of locally advanced or metastatic (Stage IIIB or IV), EGFR mutation positive, NSCLC. The PBAC considered treatment with osimertinib provided an improvement in progression free survival, overall survival and safety compared to treatment with PBS listed EGFR tyrosine kinase inhibitors.</p> <p>The PBAC recommended listing based on the incremental cost-effectiveness ratio proposed in the Sponsor's pre-PBAC response.</p>
<p>PARACETAMOL</p> <p>Suppositories 500 mg, 24</p> <p>Panadol®</p> <p>Glaxosmithkline Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Palliative care</p>	<p>To request a change to the PBS listing with amended packaged quantity and a price change.</p>	<p>The PBAC recommended the listing of paracetamol suppositories 500 mg, 10 (Panadol® 10) with the same conditions as the currently listed paracetamol suppositories 500 mg, 24 (Panadol® 24) with an increased maximum quantity of 10 packs. The PBAC recommended listing based on the importance of continued access to paracetamol suppository products for a small, targeted group of palliative care patients for whom the product is currently subsidised. The PBAC considered that the cost effectiveness of Panadol® 10 would be acceptable if it was priced with a small premium and that the price of Panadol® 24 should also be negotiated to allow for proportional pricing of this pharmaceutical item.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>PROTEIN FORMULA WITH VITAMINS AND MINERALS, LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A</p> <p>Oral liquid 125 mL, 24</p> <p>Renastep®</p> <p>Vitaflo Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Chronic renal failure (CRF)</p>	<p>Resubmission to request the Authority Required (STREAMLINED) listing of Renastep® for the dietary management of children aged 3-18 years with CRF.</p>	<p>The PBAC recommended the listing of Renastep® for the treatment of CRF for patients aged 3 or older on a cost-minimisation basis per calorie of energy equivalent compared with Kindergen®.</p>
<p>QUADRIVALENT INFLUENZA VACCINE, SPLIT VIRION, INACTIVATED</p> <p>Injection 0.5 mL</p> <p>Fluarix Tetra®</p> <p>Glaxosmithkline Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Prevention of seasonal influenza</p>	<p>To request that Fluarix Tetra® be included on the National Immunisation Program (NIP) for infants and young children aged 6 months to 5 years of age eligible for free vaccination under the NIP for the prevention of seasonal influenza.</p>	<p>The PBAC recommended an extension to the listing of Fluarix Tetra®, for the prevention of seasonal influenza, to include healthy children aged 6 months to <5 years who are currently eligible for influenza vaccination under the NIP. The PBAC recommended listing on a cost-minimisation basis compared with the nominated comparators (Vaxigrip Tetra® and FluQuadri®).</p> <p>Overall, the PBAC considered it was reasonable to conclude that the effectiveness of Fluarix Tetra® would be similar to that of Vaxigrip Tetra® or FluQuadri® for the prevention of seasonal influenza in all children aged 6 months to <5 years, and that there are likely no substantive differences in safety between Fluarix Tetra® and other NIP listed quadrivalent influenza vaccines in this population.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>RIVAROXABAN</p> <p>Tablet 2.5 mg</p> <p>Xarelto®</p> <p>Bayer Australia</p> <p>New listing (Minor Submission)</p>	<p>Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD)</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients at high risk of recurrent cardiovascular events with CAD or PAD who meet certain conditions.</p>	<p>The PBAC recommended the listing of rivaroxaban for the treatment of patients at high risk of recurrent cardiovascular events with CAD or PAD and additional high-risk factors.</p> <p>The PBAC considered that there is a moderate clinical need in this patient population, and that there are important clinical benefits associated with rivaroxaban therapy including a reduction in heart attacks, strokes and cardiovascular death.</p> <p>The PBAC considered that the cost-effectiveness of rivaroxaban would likely be acceptable at the price proposed in the minor submission, and that the Risk Sharing Arrangement proposed would appropriately mitigate the risk of excess financial impact of the listing due to uncertain patient numbers, as well as potential use outside the restriction.</p>
<p>SELEXIPAG</p> <p>Tablet 200 microgram Tablet 400 microgram Tablet 600 microgram Tablet 800 microgram Tablet 1 mg Tablet 1.2 mg Tablet 1.4 mg Tablet 1.6 mg</p> <p>Uptravi®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Pulmonary arterial hypertension (PAH)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program - Public and Private Hospitals) Authority Required listing for PAH as a sequential add-on therapy to an endothelin receptor antagonist (ERA) and a phosphodiesterase type 5 (PDE-5i).</p>	<p>The PBAC recommended the listing of selexipag for the treatment patients with World Health Organisation (WHO) Functional Class (FC) III or IV PAH. The recommendation for selexipag is as triple therapy in combination with an ERA and a PDE-5i.</p> <p>The PBAC considered the claim that selexipag, when used in combination with an ERA and a PDE-5i in patients with WHO FC III and IV PAH, was superior to placebo was reasonable, but that the magnitude of the benefit was uncertain. The PBAC considered that selexipag was inferior to placebo with regards to comparative safety.</p> <p>The PBAC had concerns regarding the modelled evaluation including clinical data limitations, uncertainty surrounding the magnitude of the clinical benefit and structural issues. The PBAC considered that given the model uncertainties, the inputs for the base case analysis should be conservative. With conservative inputs, the PBAC considered the incremental cost-effectiveness ratio was unacceptably high, but considered this could be addressed through a price reduction. The PBAC noted that the listing of selexipag could not be finalised prior to the listing of ERA/PDE-5i dual therapy, which was recommended as part of the Post-market Review of PAH listings.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>SIPONIMOD</p> <p>Tablet 250 micrograms Tablet 2 mg</p> <p>Mayzent®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>New listing (Major Submission)</p>	<p>Multiple sclerosis (MS)</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with a history of relapsing forms of MS who meet certain conditions.</p>	<p>The PBAC recommended the listing of siponimod for patients with secondary progressive MS who are ambulant (with or without support). The PBAC recommended listing on a cost-minimisation basis compared with fingolimod. The PBAC considered that the cost-effectiveness of siponimod when used in a broader patient population than fingolimod was adequately addressed with a reduced price for this population.</p> <p>In making this recommendation, the PBAC noted the high clinical need for effective treatments for patients with progressive forms of relapse-onset MS and for patients with greater accumulated disability. The PBAC recommended that additional financial measures would be required to facilitate a listing.</p>
<p>TERBUTALINE</p> <p>Powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 120 doses</p> <p>Bricanyl® Turbuhaler</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Bronchospasm</p>	<p>To request the Authority Required (STREAMLINED) listing of a new terbutaline inhaler device under the same conditions as the current inhaler presentation.</p>	<p>The PBAC recommended the listing of a new form of terbutaline, M3 Turbuhaler, under the same eligibility criteria as the currently listed form of terbutaline, M2 Turbuhaler.</p>
<p>TIOTROPIUM</p> <p>Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)</p> <p>Spiriva® Respimat®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chronic obstructive pulmonary disease Severe asthma</p>	<p>To request a change to the PBS listing to amend the device to a reusable inhaler device with a refill cartridge containing tiotropium.</p>	<p>The PBAC held no objections to the planned discontinuation of the existing Spiriva® Respimat® product and its replacement with an updated product, whereby the inhaler device would be reusable (for up to 6 cartridges) and the dose counter would be located on the cartridge rather than the inhaler device. The PBAC noted that no changes to the PBS eligibility criteria for the existing three Spiriva® Respimat® listings were proposed.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>TIOTROPIUM WITH OLODATEROL</p> <p>Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses</p> <p>Spiolto® Respimat®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chronic obstructive pulmonary disease</p>	<p>To request a change to the PBS listing to amend the device to a reusable inhaler device with a refill cartridge containing tiotropium and olodaterol.</p>	<p>The PBAC held no objections to the planned discontinuation of the existing Spiolto® Respimat® product and its replacement with an updated product, whereby the inhaler device would be reusable (for up to 6 cartridges) and the dose counter would be located on the cartridge rather than the inhaler device. The PBAC noted that no changes to the PBS eligibility criteria for the existing Spiolto® Respimat® listing were proposed.</p>
<p>TOPOTECAN</p> <p>Solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride)</p> <p>Topotecan Accord®</p> <p>Accord Healthcare</p> <p>New listing (Minor Submission)</p>	<p>Metastatic ovarian cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy (EFC) Program), Authority Required (STREAMLINED) listing of a generic brand of topotecan under the same conditions as the existing brand Hycamtin®.</p>	<p>The PBAC recommended the listing of a new form of topotecan, Topotecan Accord®, as an unrestricted benefit, on the basis that it should be available only under special arrangements under Section 100 (EFC).</p>
<p>TRIGLYCERIDES MEDIUM CHAIN FORMULA</p> <p>Oral powder 400 g</p> <p>Monogen®</p> <p>Nutricia 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 of Monogen® for all indications for which it is currently PBS listed.</p>	<p>The PBAC recommended continuing the listing of Monogen® on the PBS following its reformulation.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>VENETOCLAX</p> <p>Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg</p> <p>Tablet 10 mg Tablet 50 mg Tablet 100 mg</p> <p>Venclexta®</p> <p>AbbVie Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chronic lymphocytic leukaemia (CLL)</p>	<p>Resubmission to request an Authority Required (telephone/electronic) listing, in combination with obinutuzumab, for the first-line treatment of patients with CLL who have coexisting conditions and are unsuitable for fludarabine based chemotherapy.</p>	<p>The PBAC recommended listing of venetoclax in combination with obinutuzumab for the first-line treatment of patients with CLL who have coexisting conditions and are unsuitable for fludarabine based chemotherapy. The PBAC was satisfied that venetoclax + obinutuzumab provides, for some patients, an improvement in efficacy over current first-line CLL therapies in delaying progression.</p> <p>The PBAC considered the issues raised at the March 2020 meeting regarding the estimated cost-effectiveness and financial implications were adequately addressed, and recommended listing on a cost-effectiveness basis compared with chlorambucil + obinutuzumab. The PBAC advised that a Risk Sharing Arrangement would be required that ensures the cost offsets from reduced use of treatments in the existing later-line setting are realised.</p>
<p>VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE</p> <p>Oral powder 200 g</p> <p>Paediatric Seravit®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Dietary management of conditions requiring a highly restrictive therapeutic diet</p>	<p>To request a formulation change of Paediatric Seravit® for the dietary management of conditions requiring a highly restrictive therapeutic diet.</p>	<p>The PBAC recommended continuing the listing of Paediatric Seravit® for the dietary management of conditions requiring a highly restrictive therapeutic diet in infants and young children following its reformulation due to changes in European compositional standards.</p>

JULY 2020 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE</p> <p>Oral powder 400 g</p> <p>Kindergen®</p> <p>Nutricia Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chronic Renal Failure (CRF)</p>	<p>To request a formulation change of Kindergen® for the dietary management of CRF.</p>	<p>The PBAC recommended continuing the listing of Kindergen® for the dietary management of CRF in infants and young children following its reformulation due to changes in European compositional standards.</p>