JULY 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
AFLIBERCEPT Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) pre-filled syringe Eylea® Bayer Australia Ltd Change to listing (Major submission)	Subfoveal choroidal neovascularisation (CNV)	To request an Authority Required listing for the treatment of patients with subfoveal CNV secondary to pathologic myopia (mCNV).	The PBAC recommended the Authority Required listing of aflibercept for the treatment of subfoveal mCNV. The PBAC recommended the listing of aflibercept on a cost-minimisation basis with ranibizumab and advised that the equi-effective doses for mCNV were aflibercept 2 mg injection and ranibizumab 0.5 mg injection.
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID Sachets containing oral powder 12.5 g, 30 (PKU Explore 5) Sachets containing oral powder 25 g, 30 (PKU Explore 10) PKU Explore® Vitaflo Australia Pty Ltd New listing (Minor submission)	Phenylketonuria (PKU)	To request a Restricted Benefit listing for the dietary management of PKU.	The PBAC recommended the Restricted Benefit listing of two new forms of amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid (PKU Explore 5 and PKU Explore 10) for the dietary management of PKU on a cost minimisation basis to PKU Anamix First Spoon® at an equivalent cost per gram of protein equivalent.

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APREPITANT Capsule 165 mg Apotex® Apotex Pty Ltd New listing (Minor submission)	Nausea and vomiting	To request a Section 100 (Efficient Funding of Chemotherapy – Related Benefits) and General Schedule Authority Required (STREAMLINED) listings of a new brand Aprepitant Apotex® for the same indication as the currently listed brand, Emend®	The PBAC recommended a Section 100 (Efficient Funding of Chemotherapy – Related Benefits) and General Schedule Authority Required (STREAMLINED) listing of a new brand of aprepitant (Aprepitant Apotex®) for the same indication as the currently listed brand, Emend®.
BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® Amgen Australia Pty Limited Change to listing (Minor Submission)	Acute lymphoblastic leukaemia (ALL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of B-cell precursor ALL in patients with haematological complete remission with minimal residual disease following chemotherapy.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required listing of blinatumomab for the treatment of patients with B-cell precursor (ALL) in haematological complete remission with minimal residual disease (MRD) following induction chemotherapy. The PBAC considered that the updated data from the final analysis of the single-arm BLAST study reinforced that blinatumomab may be associated with an overall survival advantage. The PBAC was satisfied that blinatumomab would be sufficiently cost-effective in the MRD treatment setting with the proposed Risk Sharing Arrangement.

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CARMELLOSE Eye drops containing carmellose sodium 5 mg per mL, 10 mL Evolve® carmellose HYPROMELLOSE Eye drops containing hypromellose 3 mg per mL, 10 mL Evolve® hypromellose Contact Lens Centre Australia Ltd Change to recommended listing (Minor Submission)	Severe dry eye syndrome	Resubmission to request an Authority Required (STREAMLINED) listing for treatment of severe dry eye syndrome.	The PBAC recommended the Authority Required (STREAMLINED) listing of carmellose (Evolve® carmellose 0.5%) and hypromellose (Evolve® hypromellose 0.3%) multi-dose preservative-free eye drops for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops. The PBAC considered that all preservative-free eye drops were appropriate comparators and recommended that carmellose 0.5% and hypromellose 0.3% should be cost-minimised to the lowest cost PBS-listed multi-dose preservative-free eye drop.
CINACALCET Tablet 30 mg Tablet 60 mg Tablet 90 mg Pharmacor Cinacalcet® Pharmacor Pty Limited New listing (Minor Submission)	Chronic kidney disease (CKD)	To request an Authority Required (STREAMLINED) listing for the treatment of patients with secondary hyperparathyroidism in CKD.	The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required listing of cinacalcet (Pharmacor Cinacalcet®) for the treatment of secondary hyperparathyroidism in patients with CKD receiving dialysis. The PBAC considered that the requested listing should align with the previous listings for a different brand of cinacalcet (Sensipar®) and the current Kidney Disease: Improving Global Outcomes guidelines. The PBAC noted that the Therapeutic Goods Administration found that Pharmacor Cinacalcet was bioequivalent to Sensipar. Therefore, the PBAC accepted that cinacalcet was non-inferior in terms of comparative effectiveness and safety to Sensipar. The PBAC considered that cinacalcet would be cost-effective at the price recommended by the PBAC at its March 2014 meeting.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units Dysport® Ipsen Pty Ltd Change to listing (Major Submission)	Focal spasticity of the lower limb (LLFS)	Resubmission to request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe LLFS following stroke.	The PBAC recommended the Section 100 (Botulinum Toxin Program), Authority Required (STREAMLINED) listing of botulinum toxin type A (Dysport®) for LLFS following stroke or other acute neurological event on a cost minimisation basis with botulinum toxin type A (Botox®). On the basis of the indirect comparison presented, the PBAC was satisfied that Dysport® was non-inferior to Botox® in terms of comparative efficacy and safety. The PBAC considered that the equi-effective doses of Dysport® and Botox® should be based on the maximum dispensed quantities which would result in equivalent treatment costs per cycle. The PBAC considered that the equi-effective doses were: 3.75U Dysport® and 1U Botox® (i.e. 1500U Dysport® = 400U Botox®).
DABRAFENIB Capsule 50 mg Capsule 75 mg Tafinlar® TRAMETINIB Tablet 500 microgram Tablet 2 mg Mekinist® Novartis Pharmaceuticals Australia Pty Ltd Change to listing (Minor Submission)	Melanoma	Resubmission to request an Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected BRAF V600 mutation positive Stage III malignant melanoma.	The PBAC recommended the Authority Required listing of dabrafenib in combination with trametinib (dabrafenib plus trametinib) as adjuvant treatment for patients who have had completely resected BRAF V600 mutation positive Stage IIIB, IIIC or IIID malignant melanoma. The PBAC was satisfied that dabrafenib plus trametinib provides, for some patients, a significant improvement in efficacy over routine follow-up, in terms of recurrence free survival, and a likely benefit in terms of overall survival, although there are currently limited data. The PBAC considered that dabrafenib plus trametinib was inferior compared with placebo in terms of comparative safety. The PBAC noted changes that were made to the economic model and considered that the resulting incremental cost effectiveness ratio was acceptable at the proposed price. The PBAC considered that, in the context of the uncertain use across the adjuvant and unresectable or metastatic settings, a Risk Sharing Arrangement consisting of combined subsidisation caps across both adjuvant and unresectable or metastatic settings would be appropriate.

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ENOXAPARIN Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe Clexane Forte® Enoxaparin Winthrop® Clexane Forte Safety-Lock® Sanofi-Aventis Australia Pty Ltd New listing (Minor Submission)	Deep vein thrombosis	To request unrestricted benefit listing of two new strengths of enoxaparin pre-filled syringes.	The PBAC recommended listing two new strengths of enoxaparin, 120 mg and 150 mg, as an unrestricted benefit on a cost minimisation basis with the least costly alternative presentation on a per milligram basis. In making this recommendation, the PBAC considered some patients who require daily doses higher than the current available strength will have a reduced injection burden as a result of listing these new strengths.
FINGOLIMOD Capsule 250 micrograms (as hydrochloride) Gilenya® Novartis Pharmaceuticals Australia Pty Ltd New listing (Minor Submission)	Relapsing-remitting multiple sclerosis (RRMS)	To request an Authority Required listing of a new strength of fingolimod capsules for patients with RRMS, including paediatric patients.	The PBAC recommended the Authority Required listing of fingolimod 250 mcg capsules for treatment of RRMS in patients weighing 40kg or less. In making this recommendation, the PBAC considered that fingolimod 250 mcg used in RRMS patients weighing 40kg or less was equivalent to fingolimod 500 mcg used in RRMS patients weighing more than 40kg.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
FLUTICASONE FUROATE Powder for oral inhalation in breath actuated device containing fluticasone furoate 50 micrograms per dose, 30 doses Arnuity Ellipta® GlaxoSmithKline Australia Pty Ltd New listing (Minor Submission)	Asthma	To request an Unrestricted Benefit listing for a new strength of fluticasone furoate.	The PBAC recommended the listing of fluticasone furoate 50 micrograms per dose as an unrestricted benefit. The PBAC recommended the listing on a cost-minimisation basis to fluticasone propionate 100 micrograms twice daily.
GALCANEZUMAB Injection 120 mg in 1 mL single use pre-filled pen Emgality® Eli Lilly Australia Pty Ltd New listing (Major Submission)	Chronic migraine	To request an Authority Required (STREAMLINED) listing for the prophylactic treatment of patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications.	The PBAC recommended the Authority Required (STREAMLINED) listing of galcanezumab 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 galcanezumab was an alternative treatment to botulinum toxin type A (Botox®) for patients with chronic migraine and provided a similar reduction in migraine headache days. The PBAC considered the cost minimisation analysis should be based on equi-effective doses of 120 mg galcanezumab every 30 days and 164IU of Botox every 12 weeks over 2 years of treatment. Additionally, the PBAC considered it would be appropriate for galcanezumab and Botox to be combined in the same subsidisation caps under a Risk Sharing Arrangement.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 35 g, 30 (TYR Sphere 20) TYR Sphere 20® Vitaflo Australia Pty Ltd New listing (Minor Submission)	Tyrosinaemia	To request a Restricted Benefit listing for the dietary management of patients with tyrosinaemia.	The PBAC recommended the listing of the glycomacropeptide formula TYR Sphere 20 for the dietary management of tyrosinaemia. The recommendation is on a cost minimisation basis with similar alternatives per gram of protein equivalent.
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE Oral liquid 250 mL, 18 PKU GMPro LQ® Nutricia Australia Pty Ltd New listing (Minor Submission)	Phenylketonuria (PKU)	To request a Restricted Benefit listing for the dietary management of PKU.	The PBAC recommended the listing of the glycomacropeptide formula PKU GMPro LQ® for the dietary management of PKU. PKU GMPro LQ® is a liquid formulation of PKU GMPro, a powder formulation of the same glycomacropeptide formula recommended by the PBAC at its November 2018 meeting.

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INFLUENZA QUADRIVALENT VACCINE Injection 0.5 mL Vaxigrip Tetra™ Sanofi-Aventis Australia Pty Ltd New listing (Major Submission)	Prevention of seasonal influenza	To request listing on the National Immunisation Program (NIP) for the population already eligible for seasonal influenza vaccination with other brands of influenza vaccine and to extend the population eligible for seasonal influenza vaccination through the NIP to include all children aged 6 months to <5 years.	The PBAC recommended the listing of quadrivalent influenza vaccine (QIV, Vaxigrip Tetra™) on the NIP for the prevention of seasonal influenza in children aged 6 months to <5 years as well as for individuals who are currently eligible for seasonal influenza vaccination through the NIP The PBAC's recommendation for listing was based on, among other matters, its assessment, that: • QIV (Vaxigrip Tetra™) provides, for some patients, a significant improvement in efficacy over placebo and was likely to be acceptably cost-effective at the price proposed by the submission for children aged 6 months to <5 years who are not currently eligible through the NIP; and • QIV (Vaxigrip Tetra™) is non-inferior to currently listed QIVs for the population currently eligible through the NIP, with the equi-effective doses being one dose of 0.5 mL Vaxigrip Tetra™ and one dose of an alternative QIV, such as 0.5 mL FluQuadri or 0.25 mL FluQuadri Junior.
LENALIDOMIDE Capsule 5 mg Capsule 10 mg Capsule 15 mg Revlimid® Celgene Pty Ltd Change to listing (Minor Submission)	Multiple myeloma (MM)	Resubmission to request an extension to the Section 100 (Highly Specialised Drug Program) Authority Required listing to include maintenance treatment of patients with newly diagnosed MM who have undergone an autologous stem cell transplant.	The PBAC recommended the Section 100 (Highly Specialised Drug Program) Authority Required listing of lenalidomide as monotherapy for the maintenance treatment of patients with newly diagnosed MM who have undergone an autologous stem cell transplant. The PBAC considered the incremental cost effectiveness ratio was acceptable at the price proposed in the resubmission. The PBAC advised that in the context of the high and uncertain cost of lenalidomide for this indication, it would be appropriate for the listing to be implemented in conjunction with expenditure caps through a Risk Sharing Arrangement. The PBAC further advised that the current expenditure caps for lenalidomide in the relapsed refractory MM setting should be reduced, consistent with the submission's claim that the use of lenalidomide as maintenance therapy will reduce the use of lenalidomide as a treatment for relapsed refractory disease.

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LISDEXAMFETAMINE Capsule containing lisdexamfetamine dimesilate 20 mg Capsule containing lisdexamfetamine dimesilate 40 mg Capsule containing lisdexamfetamine dimesilate 60 mg Vyvanse® Shire Australia Pty Ltd New listing (Minor Submission)	Attention deficit hyperactivity disorder (ADHD)	To request Authority Required listing of three new strengths of lisdexamfetamine for the treatment of patients with ADHD.	The PBAC recommended the Authority Required listings for three new strengths of lisdexamfetamine for the treatment of patients with ADHD. The PBAC considered that the new strengths of lisdexamfetamine will provide greater dosing flexibility to achieve optimal efficacy and tolerability for patients. The PBAC noted a number of consumer comments regarding the current age of diagnosis criterion for ADHD. The PBAC considered that this was outside the scope of the submission's request, and that a minor submission including financial impacts would be required for the PBAC to review the age of diagnosis in the restriction.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
LUMACAFTOR WITH IVACAFTOR Sachet containing granules, lumacaftor 100 mg with ivacaftor 125 mg Sachet containing granules, lumacaftor 150 mg with ivacaftor 188 mg Orkambi® 100/125 and Orkambi® 150/188 Vertex Pharmaceuticals (Australia) Pty Ltd New listing (Major Submission)	Cystic fibrosis (CF)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients aged 2 years or older who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene.	The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required listing of a new presentation of lumacaftor with ivacaftor, in the form of granules, for the treatment of CF in patients aged 2 years or over who are homozygous for the F508del mutation in the CFTR gene. The PBAC accepted the clinical place for lumacaftor/ivacaftor as an add-on to current best supportive care (BSC) for patients aged 2 to 5 years, and considered that BSC (followed by treatment initiation with lumacaftor with ivacaftor tablets from 6 years of age) was the appropriate comparator. The PBAC considered that the supporting evidence for the new population of patients aged 2 to 5 years was limited but acknowledged the difficulties in obtaining efficacy data from paediatric patients. Overall, the PBAC considered that the claim of superior efficacy over BSC in patients aged 2 to 5 years was biologically plausible. However, the PBAC considered that as the incremental benefit of commencing treatment with lumacaftor with ivacaftor from an earlier age was unknown, the cost-effectiveness of commencing treatment earlier was also unknown. The PBAC advised that lumacaftor with ivacaftor granules should be listed for patients aged 2 years and older under the current Risk Sharing Arrangement for lumacaftor with ivacaftor with no additional cost to Government.
MUPIROCIN Nasal ointment 20 mg (as calcium) per gram, 5 g Medsurge Mupirocin Nasal Ointment® Medsurge Healthcare Pty Ltd New listing (Minor Submission)	Staphylococcus aureus infection	To request an Authority Required (STREAMLINED) listing of a new form of mupirocin nasal ointment in a larger pack size of 5g for the treatment of Aboriginal or Torres Strait Islander persons with Staphylococcus aureus (golden staph) infection of the nasal cavity.	The PBAC recommended the Authority Required (STREAMLINED) listing of a new form of mupirocin 2% nasal ointment in a 5g pack size (Medsurge) as an alternative to the currently listed mupirocin 2% nasal ointment, 3g pack size (Bactroban®) for the treatment of nasal colonisation of staphylococcus aureus infection in Aboriginal and Torres Strait Islander persons.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
NATALIZUMAB Solution concentrate for I.V. infusion 300 mg in 15 mL Tysabri® Biogen Australia Pty Ltd Change to listing (Minor Submission)	Relapsing-remitting multiple sclerosis (RRMS)	To request the removal of age restrictions from the existing listing for the treatment of RRMS to permit use of natalizumab in all ages.	The PBAC recommended removal of the age restriction from the PBS listing of natalizumab to permit use in paediatric patients with RRMS.
OCTREOTIDE Injection (modified release) 30 mg (as acetate), vial and diluent syringe Sandostatin® Novartis Pharmaceuticals Australia Pty Ltd Change to listing (Major Submission)	Non-functional neuroendocrine tumours of midgut or suspected midgut origin	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of unresectable locally advanced or metastatic, non-functional neuroendocrine tumour (NET) of midgut or suspected midgut origin.	The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for octreotide on a cost minimisation basis with lanreotide for the treatment of patients with non-functional gastroenteropancreatic NET (GEP-NET) tumour, in line with the current restriction for lanreotide. The PBAC noted that the submission positioned octreotide as an alternative treatment to lanreotide in the first-line treatment of patients with metastatic or non-resectable non-functional midgut NET (a sub-set of non-functional GEP-NET) based on the patient population in the key trial for octreotide, PROMID. The PBAC noted that both drugs, as somatostatin analogues, have the same mode of action. The PBAC therefore considered that if octreotide and lanreotide result in similar clinical outcomes for the sub-set of non-functional midgut NET, it would be biologically plausible to also expect similar clinical outcomes for the broader group of non-functional GEP-NET. The PBAC therefore considered that the appropriate clinical place for octreotide was as an alternative therapy for the treatment of patients with non-functional GEP-NET. The PBAC considered that the equi-effective doses are octreotide 30 mg every 28 days and lanreotide 120 mg every 28 days. The PBAC was of the view that this listing should be at worst cost neutral for Government.

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OXYCODONE Capsule containing oxycodone hydrochloride 5 mg, 10 OxyNorm® Mundipharma Pty Limited New listing (Minor Submission)	Severe disabling pain	To request a Restricted Benefit listing for a new maximum quantity of 10 for 5 mg oxycodone tablets and capsules.	The PBAC recommended the Restricted Benefit listing for a new maximum quantity for all brands of 10 oxycodone 5 mg capsules and tablets for short-term use in patients with severe disabling pain who are responsive to non-opioid analgesics. Oxycodone 5 mg capsules and tablets are currently available on the PBS in a maximum quantity of 20 capsules or tablets. The PBAC acknowledged the potential quality use of medicine benefit of reduced maximum quantities for opioids used in the acute pain setting (e.g. after surgery).
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd Change to listing (Major Submission)	Non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing, in combination with platinum chemotherapy and pemetrexed, for the first-line treatment of Stage IV non-squamous NSCLC.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of pembrolizumab in combination with platinum chemotherapy and pemetrexed for the treatment of patients with Stage IV non-squamous NSCLC, who are epidermal growth factor receptor wild type, and negative for anaplastic lymphoma kinase or c-ROS proto-oncogene 1 receptor tyrosine kinase gene rearrangements, regardless of programmed death-ligand 1 (PD-L1) tumour proportion score (TPS) status (<50% or ≥50%). The PBAC considered a small reduction in the price proposed by the sponsor was required to address the outstanding uncertainties regarding the cost-effectiveness of pembrolizumab+platinum+pemetrexed, regardless of PD-L1 TPS status. The PBAC considered it would be appropriate for the listing to join the existing Risk Sharing Arrangements for PD-(L)1 inhibitors, with a modest expansion in the subsidisation caps.
RISANKIZUMAB Injection 75 mg in 0.83 mL pre-filled syringe Skyrizi® AbbVie Pty Ltd New listing (Major Submission)	Chronic plaque psoriasis	To request an Authority Required listing for the treatment of patients with severe chronic plaque psoriasis.	The PBAC recommended the Authority Required listing of risankizumab for the treatment of patients with severe chronic plaque psoriasis on a cost-minimisation basis with the least costly biologic currently listed on the PBS for chronic plaque psoriasis.

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SAPROPTERIN Powder for oral liquid 100 mg (as dihydrochloride), Powder for oral liquid 500 mg (as dihydrochloride) Tablet (soluble) containing sapropterin dihydrochloride 100 mg Kuvan® BioMarin Pharmaceutical Australia Pty Ltd New listing (Minor Submission)	Hyperphenylalaninaemia (HPA)	To request the Authority Required listing of two new forms of sapropterin for the treatment of HPA in patients with tetrahydrobiopterin (BH4) deficiency; and in patients with phenylketonuria (PKU). To request a change to the existing listing from Authority Required (Written) to Authority Required (Telephone) for the treatment of HPA in patients with BH4 deficiency.	The PBAC recommended the listing of a 100 mg and 500 mg powder for oral solution form of sapropterin for HPA due to BH4 deficiency and HPA due to PKU. The PBAC also recommended the change in authority level of the current listing for sapropterin for HPA due to BH4 from Authority Required (in writing) to Authority required (telephone) on the basis that there was no longer a risk for leakage into the PKU population. The PBAC also recommended that nurse practitioners should be able to prescribe sapropterin for HPA due to BH4 deficiency as a continuing treatment.
SODIUM PHENYLBUTYRATE Granules 483 mg (as sodium) per g, 174 g Pheburane® Orpharma Pty Ltd New listing (Minor Submission)	Urea cycle disorder (UCD)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with UCD.	The PBAC recommended the Authority Required (STREAMLINED) listing of a sugar-coated granule formulation of sodium phenylbutyrate for the chronic treatment of patients with UCD. The PBAC considered that the issues raised in the March 2019 submission had been addressed, that is, a first-line setting for the proposed listing, a significantly reduced proposed price, and revised financial estimates.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TRASTUZUMAB Powder for I.V. infusion 150 mg Herzuma® Celltrion Healthcare Australia Pty Ltd. New listing (Minor Submission)	Breast cancer Gastric cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.	The PBAC recommended the Section 100 (Efficient Funding Chemotherapy Program) Authority Required (STREAMLINED) listing of the biosimilar brand of trastuzumab, Herzuma, for all indications for which the trastuzumab reference brand (Herceptin) is currently PBS-listed. 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. The PBAC advised that all PBS-listed brands of trastuzumab should be made Authority Required (STREAMLINED) across all indications.
TRASTUZUMAB Powder for I.V. infusion 60 mg Powder for I.V. infusion 150 mg Powder for I.V. infusion 420 mg Kanjinti® Amgen Australia Pty Ltd	Breast cancer Gastric cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing of the biosimilar brand of trastuzumab, Kanjinti, for all indications for which the trastuzumab reference brand (Herceptin) is currently PBS-listed. 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. The PBAC advised that all PBS-listed brands of trastuzumab should be made Authority Required (STREAMLINED) across all indications.
TYROSINE WITH CARBOHYDRATE Sachets of oral powder 4 g containing 1 g tyrosine, 30 (Tyrosine 1000) Tyrosine 1000® Vitaflo Australia Pty Ltd Change to listing (Minor Submission)	Phenylketonuria	To request a change to the existing listing to reflect a change in the recommended age indication from "suitable from birth" to “suitable from 3 years of age” due to product formulation changes.	The PBAC recommended a change to the listing of tyrosine with carbohydrate (Tyrosine 1000) to indicate that the formulation is suitable for patients aged 3 years and over.