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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ABIRATERONE Tablet containing abiraterone acetate 500 mg Zytiga® Janssen-Cilag Pty Ltd New listing (Minor Submission)	Castration resistant metastatic carcinoma of the prostate	To request an Authority Required listing of a new form of abiraterone.	The PBAC recommended the Authority Required (STREAMLINED) listing of abiraterone acetate tablet for use in combination with a corticosteroid for the treatment of metastatic castration-resistant carcinoma of the prostate noting that the listing would reduce the pill burden for some patients.
ADALIMUMAB Injection 40 mg in 0.8mL vial Humira® Abbvie Pty Ltd New listing (Minor Submission)	Same as currently PBS subsidised indications for adalimumab	To request an Authority Required General Schedule and Section 100 (Highly Specialised Drug) listing for a new form of adalimumab.	The PBAC recommended the Authority Required listing of adalimumab 40 mg vial form, with the same restrictions as the currently listed cartridge and syringe forms of adalimumab. In making this recommendation, the PBAC noted that although the application for the vial form of adalimumab met the requirements for a positive PBAC recommendation, the evidence that there is a clinical need for a vial presentation of adalimumab is not convincing.
ALECTINIB Capsule 150 mg Alecensa® Roche Products Pty Ltd New listing (Major Submission)	Non-small cell lung cancer (NSCLC)	To request an Authority Required listing for the treatment of patients with locally advanced or metastatic NSCLC under certain conditions.	The PBAC recommended the telephone Authority Required General Schedule listing of alectinib for the treatment of anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer (NSCLC) on a cost-minimisation basis against ceritinib. In making this recommendation, the PBAC considered the effectiveness of alectinib in a relatively small population of ALK-positive NSCLC patients, and the clinical need for additional targeted therapies with different safety profiles than currently available treatments for this condition. The PBAC considered that the submission's claim of non-inferiority for efficacy and safety against ceritinib in pre-treated metastatic NSCLC patients was reasonable, and therefore a cost-minimisation approach against ceritinib was appropriate.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
AMINO ACID FORMULA supplemented with PREBIOTICS, PROBIOTICS and LONG CHAIN POLYUNSATURATED FATTY ACIDS Oral powder, 400 g (Neocate Syneo) Neocate® Syneo™ Nutricia Australia Pty Ltd New listing (Minor Submission)	Cows' milk protein enteropathy Severe cows' milk protein enteropathy with failure to thrive Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Cows' milk anaphylaxis Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Severe intestinal malabsorption including short bowel syndrome Eosinophilic oesophagitis	To request an Authority Required listing for infants (up to 24 months) for the treatment of cows' milk protein enteropathy; severe cows' milk protein enteropathy with failure to thrive; combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae; proven combined immunoglobulin E mediated allergy to cows' milk protein and soy protein; eosinophilic eosophagitis; cows' milk anaphylaxis; and severe intestinal malabsorption including short bowel syndrome.	The PBAC recommended the Authority Required listing of Neocate Syneo® for the treatment of: Cows' milk anaphylaxis; cows' milk protein enteropathy; severe cows' milk protein enteropathy with failure to thrive; combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae; proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein; severe intestinal malabsorption including short bowel syndrome; and eosinophilic oesophagitis (EoE)on a cost-minimisation basis against Neocate Gold® at an equivalent price per kilojoule basis.
AMINO ACID FORMULA with VITAMINS and MINERALS WITHOUT PHENYLALANINE Oral liquid 125 mL, 30 (PKU Lophlex LQ 20) Sachets containing oral powder 27.8 g, 30 (Lophlex) PKU Lophlex® LQ 20 Lophlex® Nutricia Australia Pty Ltd New listing (Minor Submission)	Phenylketonuria	To request Restricted Benefit listings of two forms of amino acid based formulations for the treatment of patients with phenylketonuria.	The PBAC recommended increasing the maximum quantities of PKU Lophlex LQ20® and PKU Lophlex® per script for the treatment of phenylketonuria to align with other similar products on the PBS, as requested by the submission.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BACLOFEN Intrathecal injection 40 mg in 20 mL Sintetica Baclofen Intrathecal® Boucher & Muir Pty Ltd New listing (Minor Submission)	Severe chronic spasticity	To request a Section 100 (Highly Specialised Drugs Program) listing of a new form of baclofen.	The PBAC recommended a Section 100 Highly Specialised Drugs (HSD) Public Hospital Authority Required (STREAMLINED) listing and a Section 100 HSD Private Hospital Authority Required listing of a new strength of baclofen (40 mg in 20 mL ampoule) for the treatment of severe chronic spasticity, the same indication as the currently listed 10 mg in 5 mL ampoules.
CARFILZOMIB Powder for I.V. infusion 30 mg Powder for I.V. infusion 60 mg Kyprolis® Amgen Australia Pty Ltd New listing (Major submission)	Multiple myeloma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for carfilzomib in combination with dexamethasone for the treatment of patients with multiple myeloma who have failed at least one prior line of treatment.	The PBAC recommended the listing of carfilzomib for use in combination with dexamethasone (Cd) in patients with relapsed/refractory multiple myeloma, on the basis that the claim of superior comparative effectiveness of Cd over bortezomib in combination with dexamethasone (Bd) was supported by the updated clinical trial data, with a clinically meaningful overall survival advantage. The PBAC noted clinical trial data from the ENDEAVOR trial that indicated a statistically significant improvement in median progression free survival of 7.5 months and median overall survival of 7.6 months for Cd, compared to Bd. The PBAC is satisfied that carfilzomib provides, for some patients, a significant improvement in efficacy over bortezomib when in combination with dexamethasone and a different and inferior safety profile. The PBAC agreed that at the incremental cost-effectiveness ratio (ICER) presented in the submission of $45,000 - 75,000, Cd could be considered cost-effective in the context of adjustments to the model to account for the effective price of bortezomib and administration costs.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ECULIZUMAB Solution concentrate for I.V. infusion 300 mg in 30 mL Soliris® Alexion Pharmaceuticals Australasia Pty Ltd Change to listing (Minor Submission)	Atypical haemolytic uraemic syndrome (aHUS) in end stage renal disease (ESRD)	Resubmission to request an extension to the Authority Required listing for the treatment of patients with aHUS in ESRD who are eligible for a renal transplant.	The PBAC recommended extending the listing of eculizumab, on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program): Authority Required (written) listing for the prevention of atypical haemolytic uraemic syndrome (aHUS) in patients at moderate-high risk of recurrence who have received a renal allograft for ESRD due to aHUS, irrespective of whether they have previously been successfully treated with eculizumab for aHUS. The PBAC recommended prescribing should be restricted to prescribing by a nephrologist or a paediatric nephrologist within a transplant unit. The PBAC considered that in-patient treatment should not be subsidised by the PBS and that initial treatment in this setting should be limited to 3 months of treatment post-transplant (comprising the period of in-patient treatment plus 10 weeks of treatment under the PBS) as this is the highest risk period for thrombotic microangiopathy (TMA) recurrence. The PBAC considered despite the lack of robust clinical trial evidence, the registry data along with a series of individual case studies provided enough support for the PBAC to be satisfied that eculizumab reduces the risk of recurrence of aHUS following kidney transplantation and hence graft loss, however the committee were unable to precisely quantify the incremental benefit over other treatment options.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
EPOETIN LAMBDA Injection 1,000 units in 0.5 mL pre-filled syringe Injection 2,000 units in 1 mL pre-filled syringe Injection 3,000 units in 0.3 mL pre-filled syringe Injection 4,000 units in 0.4 mL pre-filled syringe Injection 5,000 units in 0.5 mL pre-filled syringe Injection 6,000 units in 0.6 mL pre-filled syringe Injection 8,000 units in 0.8 mL pre-filled syringe Injection 10,000 units in 1 mL pre-filled syringe Novicrit® Sandoz Pty Ltd. Change to listing (Minor Submission)	Anaemia associated with intrinsic renal disease	To request removal of the NOTE in the restriction limiting epoetin lambda to the intravenous route.	The PBAC recommended the proposed amendment of the existing restriction of epoetin lambda to remove the note “Epoetin lambda should only be administrated by the intravenous route” to allow for subcutaneous administration for the treatment of anaemia associated with intrinsic renal disease on the basis of an updated indication from the TGA Approved Production Information.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
EVOLOCUMAB Injection 420 mg in 3.5 mL single dose autoinjector Repatha® Amgen Australia Pty Ltd New listing (Minor Submission)	Familial homozygous hypercholesterolaemia	To request an Authority Required listing for a new form of evolocumab.	The PBAC recommended the listing of the new strength of evolocumab for the treatment of familial homozygous hypercholestrolaemia. The PBAC accepted that this additional form of evolocumab would provide patients with an alternative dosing schedule to the currently listed form at no additional cost to the Government.
FENTANYL Tablet (sublingual) 100 micrograms (as citrate) Tablet (sublingual) 200 micrograms (as citrate) Abstral® A.Menarini Australia Pty Ltd Change to listing (Minor Submission)	Breakthrough pain	To request an increase to the maximum quantity packs per authority script for breakthrough pain to two packs for initial treatment, to facilitate complete dose titration in patients receiving palliative care.	The PBAC recommended amending the current Authority Required listing of fentanyl citrate (Abstral®) on the Palliative Care Schedule of the PBS by increasing the maximum quantity of the 100 mcg and 200 mcg presentations from 10 to 20 tablets per script for dose titration in the initiation of treatment of cancer patients with breakthrough pain. The PBAC advised that the recommended changes to the listing would be expected to incur additional costs to the PBS. The PBAC additionally recommended future discussion regarding the growing size of titration packs and the potential issue of product diversion of this medicine which carries a high risk of dependence, but considered that, in the case of this product in this population, the risk of diversion was considered to be low.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
GLYCOMACROPEPTIDE FORMULA with LONG CHAIN POLYUNSATURATED FATTY ACIDS and DOCOSAHEXAENOIC ACID and LOW IN PHENYLALANINE Sachets containing oral powder 27 g, 30 (PKU Sphere 15) Sachets containing oral powder 35 g, 30 (PKU Sphere 20) PKU Sphere® 15 PKU Sphere® 20 Vitaflo Australia Pty Ltd New listing (Minor Submission)	Phenylketonuria	To request a name change to the current PBS listed 'PKU Sphere' and request a Restricted Benefit listing of a new form of glycomacropeptide formula (PKU Sphere15).	The PBAC recommended the listing of PKU Sphere15® as a Restricted Benefit for the dietary management of phenylketonuria on a cost-minimisation basis against Camino Pro Bettermilk® at an equivalent price per gram of protein equivalent.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
GUANFACINE Tablet containing guanfacine hydrochloride 1 mg Tablet containing guanfacine hydrochloride 2 mg Tablet containing guanfacine hydrochloride 3 mg Tablet containing guanfacine hydrochloride 4 mg Intuniv® Shire Australia Pty Ltd New listing (Major Submission)	Attention deficit hyperactivity disorder (ADHD)	To request an Authority Required listing of guanfacine for the treatment of ADHD in patients aged 6-18 years who are contraindicated to or have withdrawn from dexamfetamine, methylphenidate or lisdexamfetamine therapy; or as add-on therapy following an unsatisfactory response to optimised stimulant therapy.	The PBAC recommended the listing of guanfacine on a cost-minimisation basis with atomoxetine for the treatment of patients with attention deficit hyperactivity disorder (ADHD) who are contraindicated or intolerant to stimulant therapy. The PBAC did not recommend the listing of guanfacine as adjunctive therapy in patients who have failed to achieve an adequate response to stimulants given the uncertain clinical significance of the trial outcomes and the uncertain cost-effectiveness. The PBAC did not recommend the listing of guanfacine as monotherapy in patients who have failed to achieve an adequate response to stimulants as the evidence presented did not support a listing in that population. For the population contraindicated or intolerant to stimulants, the PBAC noted the trend toward superior efficacy and inferior safety of guanfacine in comparison with atomoxetine, based on Trial 316, and accepted the request for cost-minimisation. The PBAC noted that for adjunctive therapy in patients who have failed to achieve an adequate response to stimulants, Trial 313 showed statistically significant improvements for guanfacine+stimulants over placebo+stimulants for all outcomes, although the change in ADHD score was possibly not clinically significant. However, the PBAC considered the economic model presented was uncertain and the eligible population under the proposed restriction would be difficult to contain. Overall, the ICER was not acceptable at the price proposed.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE Injection 0.5 mL, pre-filled syringe Gardasil® 9 Seqirus (Australia) Pty Ltd New listing (Major Submission)	Prevention of human papilloma virus (HPV)	To request listing on the National Immunisation Program as a 2-dose schedule for females and males aged 12-13 years as part of a school age program for the prevention of HPV to replace the current 3-dose schedule of 4-valent HPV vaccine.	The PBAC recommended that 9-valent human papillomavirus (9vHPV) vaccine (Gardasil® 9) be made available as a designated vaccine for the purpose of funding through the National Immunisation Program as a 2-dose schedule for 12-13 year olds as part of a school based immunisation program for the prevention of HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. The recommendation was made on the basis of cost effectiveness compared with a 3 dose schedule of quadrivalent HPV (4vHPV) vaccine. The PBAC accepted that the 2-dose 9vHPV vaccine schedule is likely to provide non inferior clinical protection against disease associated with 4vHPV types (6/11/16/18) and superior clinical protection against disease associated with 9v non4vHPV types (31/33/45/52/58), compared with the 3-dose 4vHPV vaccine schedule.
ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe Firazyr® Shire Australia Pty Ltd Change to listing (Minor Submission)	Hereditary angioedema	To request a change to the current Authority Required listing to limit any authorised increase in the maximum quantity to 12 per script.	The PBAC recommended limiting increases in the maximum quantity to 12 injections per authority prescription on the basis that this would encourage further clinical review of patients experiencing a high frequency of attacks.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers Bronchitol® Pharmaxis Ltd Change to listing (Major Submission)	Cystic fibrosis	Resubmission to request a change to the current listing to allow for treatment in combination with dornase alfa in patients who are inadequately responsive to dornase alfa.	The PBAC recommended that the current Section 100 (Highly Specialised Drugs Program) listing of mannitol be amended to allow for PBS-subsidised use in combination with PBS-subsidised dornase alfa (DNase) in patients who are inadequately responsive to monotherapy with DNase. This recommendation was made in the context of the small additional patient population with complex needs, equity of access considerations regarding the current compassionate use arrangements, an expectation that clinicians are best placed to determine which patients will benefit from combination therapy.
OCRELIZUMAB Solution concentrate for I.V. infusion 300 mg in 10 mL Ocrevus® Roche Products Pty Ltd New listing (Major Submission)	Relapsing-remitting multiple sclerosis (RRMS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of RRMS.	The PBAC recommended the listing of ocrelizumab for the treatment of relapsing-remitting multiple sclerosis (RRMS) on a cost-minimisation basis with fingolimod. The PBAC recommended that ocrelizumab on that basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program – public and private hospital). The PBAC considered that based on the evidence presented, the claim that ocrelizumab has non-inferior comparative efficacy to fingolimod was adequately supported. The PBAC anticipated that ocrelizumab is likely to substitute for all currently PBS listed medicines for RRMS.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
PERAMPANEL Tablet 2 mg (as hemisesquihydrate) Tablet 4 mg (as hemisesquihydrate) Tablet 6 mg (as hemisesquihydrate) Tablet 8 mg (as hemisesquihydrate) Tablet 10 mg (as hemisesquihydrate) Tablet 12 mg (as hemisesquihydrate) Fycompa® Eisai Australia Pty Ltd Change to listing (Major Submission)	Epilepsy	Resubmission to request an Authority Required (STREAMLINED) listing for perampanel for the treatment of idiopathic generalised epilepsy with primary generalised tonic-clonic seizures under certain conditions.	The PBAC recommended the listing of perampanel for the treatment of primary generalised tonic-clonic (PGTC) seizures in patients with idiopathic generalised epilepsy (IGE), on the basis of a mixed comparison against placebo in refractory patients who have failed to respond adequately to other anti-epileptic drugs (AED); and against other AEDs (valproate, lamotrigine, levetiracetam and topiramate) for refractory patients in whom perampanel will substitute for another AED. In making this recommendation the PBAC agreed that there was a clinical need for an additional treatment option for patients with PGTC seizures. The PBAC noted that the equi-effective doses were nominated as perampanel 8 mg/day, lamotrigine 300 mg/day, levetiracetam 2000 mg/day, topiramate 300 mg/day and valproate 1500 mg/day. The PBAC considered there was uncertainty around the equi-effective doses but that overall these doses provided a reasonable basis for the cost-minimisation analysis. The PBAC did not agree that the calculation of the weighted price presented in the submission was appropriate. The PBAC considered that the proportion of perapanel use in last-line vs earlier line treatment was likely to be 30-40% and 60-70% respectively.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
RITUXIMAB Solution for subcutaneous injection containing rituximab 1400 mg in 11.7 mL Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL Mabthera® SC Mabthera® Roche Products Pty Ltd Change to listing (Minor Submission)	CD20 positive lymphoma	To consider the available evidence for the consolidation of all existing listings of rituximab for CD20 positive lymphomas.	The PBAC recommended a new, single, consolidated listing for rituximab as induction therapy in combination with PBS-subsidised chemotherapy for all CD20 positive lymphoid cancers. The PBAC also recommended a new continuing therapy listing for rituximab as maintenance therapy in combination with PBS-subsidised chemotherapy for CD20 positive acute lymphoblastic leukaemia. The PBAC recommended no change to the current PBS listings for rituximab as monotherapy for maintenance treatment of follicular B-cell non-Hodgkin's lymphoma; and re-induction treatment of relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma. In making its decision, the PBAC recalled its review of the evidence for use of rituximab in combination with chemotherapy for patients at its July 2016 meeting. It also recalled prior input from the Haematology Society of Australia and New Zealand (HSANZ), the Australasian Leukaemia & Lymphoma Group (ALLG), and consumers on the need to broaden the PBS listings, and noted the recent publication of evidence supporting use in CD20 positive acute lymphoblastic leukaemia.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
SOMATROPIN All forms and strengths All brands Endocrine Society of Australia; Australian Paediatric Endocrine Group Change to listing (Minor Submission)	Severe growth hormone deficiency	Resubmission to request a Section 100 (Growth Hormone) Authority Required listing for the treatment of adults with severe growth hormone deficiency and substantially impaired quality of life at baseline.	The PBAC recommended the listing of somatropin for the treatment of adults with severe growth hormone deficiency (GHD), and substantially impaired quality of life (QoL) at baseline, on the basis that it should be available only under special arrangements under Section 100 (Growth Hormone Program). The PBAC was satisfied that somatropin provides, for some patients, a significant improvement in efficacy over standard care. In November 2016, the PBAC had deferred its decision on listing this drug for this indication to seek further comparative analysis on the range of clinical benefits provided by somatropin, to clarify the proposed PBS restriction, and to allow the Department to discuss appropriate pricing in this setting with sponsors of somatropin products registered for use in adults. In its consideration of the present submission, the PBAC noted the narrative review of evidence in relation to the effects of somatropin on body composition, bone mineral density, cardiovascular risk, cardiorespiratory function, safety and various QoL assessment instruments. Although non-comparative, the PBAC nonetheless found that this evidence supported its previous findings concerning the clinical need and benefit of this therapy. The PBAC maintained its concerns regarding the November 2016 model inputs, which had introduced uncertainty into the ICER calculations. However, the PBAC also recalled its view that, given the high uncertainty in quantifying the clinical benefit of somatropin treatment, a reduction in drug cost would address some of the uncertainty in the cost-effectiveness of somatropin in this setting. The PBAC therefore advised that its uncertainty would be mitigated, and the cost-effectiveness of somatropin in this setting would be acceptable, at a lower ICER.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral powder 400 g (Monogen) Monogen® Nutricia Australia Pty Ltd Change to listing (Minor Submission)	Dietary management of conditions requiring a source of medium chain triglycerides	To advise the PBAC of a change to the formulation of Monogen.	The PBAC recommended the continued listing of Monogen® for the dietary management of conditions requiring a source of medium chain triglycerides, with a change in nutritional profile.
VENETOCLAX Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd New listing (Minor Submission)	Relapsed/refractory chronic lymphoid leukaemia (CLL)	Resubmission to request an Authority Required listing for the treatment of relapsed/refractory CLL.	The PBAC recommended the listing of venetoclax. Given the uncertainty in regards to the comparative effectiveness and safety of venetoclax at this stage, the PBAC recommended venetoclax on a cost-minimisation basis with idelalisib in combination with rituximab for the treatment of relapsed or refractory chronic lymphocytic leukaemia (CLL) in patients who have failed a kinase inhibitor. The PBAC considered that, based on limited evidence, venetoclax was likely to be similar in terms of effectiveness to idelalisib with rituximab in this population with residual unmet clinical need. The PBAC rejected the request to list venetoclax as a second-line treatment option in patients with relapsed or refractory CLL who have a 17p deletion. The PBAC considered that there was an insufficient basis to justify that venetoclax could substitute for ibrutinib in this population.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
VITAMINS, MINERALS and TRACE ELEMENTS FORMULA Sachets containing oral powder 7 g, 30 (Phlexy Vits) Phlexy Vits® Nutricia Australia Pty Ltd New listing (Minor Submission)	Dietary management of conditions requiring a highly restrictive therapeutic diet	To request a Restricted Benefit listing of Phlexy Vits for patients requiring a highly restrictive therapeutic diet who have been unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.	The PBAC recommended the Restricted Benefit listing of Phlexy-Vits® for the dietary management of conditions requiring a highly restrictive therapeutic diet for patients aged 3 years or older, on a cost-minimisation basis against FruitiVits® at an equivalent cost per sachet.