JULY 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Humira® AbbVie Pty Ltd New listing (Minor Submission)	Severe active rheumatoid arthritis; Sever psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Sever active juvenile idiopathic arthritis; Sever Crohn disease; Refractory fistulating Crohn disease; Moderate to severe ulcerative colitis; Moderate to severe hidradenitis suppurativa	To request an Authority Required listing for two new forms of adalimumab and to request the current Section 100 (Highly Specialised Drug) listings for juvenile idiopathic arthritis (JIA) be changed to a General Schedule listing.	The PBAC recommended Authority Required listings for two new forms and strengths of adalimumab on a cost-neutral basis to the existing forms of adalimumab. The PBAC considered that the request to amend the juvenile idiopathic arthritis (JIA) listings to General Schedule was not appropriate due to the implications for public hospital-based prescribing by paediatric rheumatologists and in paediatric rheumatology centres in non-PBS reforms states.
ADALIMUMAB Injection 20 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Amgevita® Amgen Australia Pty Limited New listing (Minor Submission)	Severe active rheumatoid arthritis; Severe psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Severe active juvenile idiopathic arthritis; Severe Crohn disease; Refractory fistulating Crohn disease; Moderate to severe ulcerative colitis; Moderate to severe hidradenitis suppurativa	To request an Authority Required listing of this biosimilar brand for all indications for which the reference biological is currently PBS listed.	The PBAC recommended the listing of the biosimilar brand of adalimumab (Amgevita®) for the same indication as the reference brand Humira. The PBAC advised that, under Section 101(4AACD) of the *National Health Act, 1953*, in the Schedule of Pharmaceutical Benefits, Amgevita®, Hadlima® and Humira® pre-filled syringes should be treated as equivalent ('a' flagged) to each other and Amgevita®, Hadlima® and Humira® cartridges should be treated as equivalent ('a' flagged) to each other, for respective PBS-listed indications for each brand. The PBAC advised that the biosimilar uptake drivers should be applied to adalimumab consistent with previous recommendations regarding the application of the drivers to other biosimilar biological medicines listed for the same indications.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL single dose autoinjector Hadlima® Merck Sharp & Dohme (Australia) Pty Ltd New listing (Minor Submission)	Severe active rheumatoid arthritis (RA)	To request an Authority Required listing of this biosimilar brand for the rheumatoid arthritis indication for which the reference biological is currently PBS listed.	The PBAC recommended the biosimilar brand of adalimumab (Hadlima®) be listed for the rheumatoid arthritis (RA) indication for which the reference product Humira® is currently PBS listed. In Australia, decisions about indication extrapolation for biosimilar medicines are made by the Therapeutic Goods Administration (TGA). The PBAC noted that rheumatoid arthritis is the only TGA-approved indication for Hadlima®, and that the sponsor had not sought to have Hadlima® TGA-registered for the remaining Humira®-approved indications at this time. The PBAC advised that, under Section 101(4AACD) of the *National Health Act, 1953*, in the Schedule of Pharmaceutical Benefits, for respective PBS-listed indications for each brand, Hadlima®, Amgevita® and Humira® pre-filled syringes should be treated as equivalent ('a' flagged) to each other and Hadlima, Amgevita and Humira cartridges should be treated as equivalent ('a' flagged) to each other. The PBAC advised that there would be no clinical or other concerns about appropriate use of medicines if the policy decision were made to apply the following uptake drivers to the RA indication: • change to the prescribing software that gives preference to biosimilar for patients naïve to treatment with adalimumab; • lower the authority level to streamlined authority for patients continuing (i.e. subsequent continuing) on biosimilar adalimumab.

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AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS, WITHOUT PHENYLALANINE AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID Oral powder 400 g Oral liquid 500 mL, 20 PKU Start® PKU Baby® Vitaflo Australia Pty Ltd Orpharma Pty Ltd Matter arising (Minor Submission)	Phenylketonuria	To provide a response to the PBAC regarding advice from the Nutritional Products Working Party (NPWP) on the total iron content in PKU Start and PKU Baby.	The PBAC recommended the Restricted Benefit listing of PKU Start® for the dietary management of phenylketonuria (PKU) on a cost-minimisation basis to PKU Anamix Infant® brand of amino acid formula, at an equivalent price per gram of protein equivalent. The PBAC also recommended the retention of the PKU Baby® on the PBS. The Committee noted these products provide a level of iron below recommended daily intake for infants and recommended that an administrative note be included in both listings to advise prescribers of the low level of iron in these products.

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APOMORPHINE Injection containing apomorphine hydrochloride 30 mg in 3 mL cartridge Apomine® Intermittent Pfizer Australia Pty Ltd New listing (Minor Submission)	Parkinson disease	To request a Section 100 (Highly Specialised Drug) listing of a new form of apomorphine.	The PBAC recommended the Section 100 (Highly Specialised Drug) Authority Required listing of a new form of apomorphine (30 mg in 3 mL) delivered in a reusable multiple dose pen injector system for the treatment of Parkinson's disease. The PBAC advised that, under Section 101 (4AACD) of the *National Health Act 1953*, Apomine Intermittent 30 mg in 3 mL injection could be treated as equivalent ('a' flagged) to Movapo Pen 30 mg in 3 mL injection (recommended at the March 2018 PBAC meeting) for the purposes of substitution at the pharmacy level. The Committee noted that Movapo is administered via a disposable injector pen, while this form (Apomine Intermittent) uses a reusable injector pen, and considered this difference could be managed through the regular patient education and counselling that is provided to patients by prescribers and pharmacists.
ARIPIPRAZOLE Powder for injection 400 mg (as monohydrate) with diluent, pre-filled syringe Abilify Maintena® Lundbeck Australia Pty Ltd New listing (Minor Submission)	Schizophrenia	To request an Authority Required (STREAMLINED) benefit for a new form of the long acting injection aripiprazole.	The PBAC recommended the Authority Required (STREAMLINED) listing of the new presentation of the currently listed aripiprazole 400 mg modified release injection for the treatment of schizophrenia.
AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mL Bavencio® Merck Serono Australia Pty Ltd (with Pfizer Australia Pty Ltd) New listing (Major Submission)	Metastatic merkel cell carcinoma (MCC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with metastatic merkel cell carcinoma (MCC).	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of avelumab for the treatment of metastatic Merkel cell carcinoma (mMCC). The PBAC acknowledged that this is an aggressive, rare form of cancer and that avelumab treatment resulted in improved progression free and overall survival rates in patients, and longer durations of response compared with currently available chemotherapy. Although noting that the data in the first line setting are limited and immature, the PBAC considered that a listing that enables use in any line of therapy would allow equitable access.

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BUDESONIDE Capsule (modified release) 3 mg Entocort® Emerge Health Pty Ltd New listing (Minor submission)	Mild to moderate Crohn disease	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn's disease.	The PBAC recommended the listing of budesonide for treatment of mild to moderate Crohn's disease affecting the ileum and/or the ascending colon. The PBAC recommended the listing on cost minimisation basis against a weighted mixed comparator of mesalazine and prednisolone. In making this recommendation, the PBAC noted the clinical need for additional treatment options in patients with mild to moderate Crohn's disease.
CARMELLOSE HYPROMELLOSE Eye drops containing carmellose sodium 5 mg per mL, 10 mL Eye drops containing hypromellose 3 mg per mL, 10 mL Evolve® carmellose Evolve® hypromellose Contact Lens Centre Australia New listing (Minor Submission)	Severe dry eye syndrome	To request an Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome.	The PBAC recommended Authority Required (STREAMLINED) listings for carmellose (Evolve® carmellose 0.5%) and hypromellose (Evolve® hypromellose 0.3%) multi-use eye drops for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives. The PBAC advised that carmellose 0.5% and hypromellose 0.3% should be cost-minimised against the lowest cost PBS-listed ocular lubricant.
CLADRIBINE Tablet 10 mg Mavenclad® Merck Serono Australia Pty Ltd New listing (Minor submission)	Relapsing remitting multiple sclerosis (RRMS)	Resubmission to request an Authority Required listing for the treatment of relapsing remitting multiple sclerosis (RRMS).	The PBAC recommended the listing of cladribine for the treatment of relapsing-remitting multiple sclerosis. The PBAC's recommendation for listing was based on, amongst other matters, its assessment than the cost-effectiveness of cladribine would be acceptable if it were cost-minimised against fingolimod.

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CLOZAPINE Oral liquid 50 mg per mL, 100 mL Versacloz® Pfizer Australia Pty Ltd New listing (Minor Submission)	Schizophrenia	To request a temporary Authority Required and Authority Required (STREAMLINED), Section 100 Highly Specialised Drugs Program (HSD) Public Hospital, Private Hospital and Community Access listings as an alternative to the currently listed clozapine (Clopine Suspension®) to address the currently supply shortage issue.	The PBAC recommended the temporary Section 100 Highly Specialised Drugs Program (HSD) and Section 100 Community Access listings of clozapine (Versacloz®) on the Pharmaceutical Benefits Scheme (PBS) to address the current supply shortage of clozapine (Clopine Suspension®, 50 mg per mL clozapine suspension).
CRIZOTINIB Capsule 200 mg Capsule 250 mg Xalkori® Pfizer Australia Pty Ltd Change to listing (Minor Submission)	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) with a ROS1 gene rearrangement confirmed by fluorescent in situ hybridisation (FISH) testing	Resubmission to request an Authority Required listing for the treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC with a ROS1 gene rearrangement confirmed by FISH testing, in patients who have failed at least one treatment with platinum based chemotherapy.	The PBAC recommended the Authority Required listing of crizotinib for the treatment of c-ROS proto-oncogene 1 (ROS1) positive locally advanced (Stage IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC). In making this recommendation, the PBAC acknowledged that there is a high unmet clinical need in the small proposed population. Further, the PBAC advised that crizotinib's effectiveness and safety profile in the ROS1-positive NSCLC population is likely to be similar to that in the ALK-positive NSCLC population, for which it is already PBS listed. The PBAC noted that the Medical Services Advisory Committee (MSAC) had foreshadowed its support for a new Medical Benefits Schedule (MBS) item for ROS1 testing to inform eligibility for crizotinib treatment in this population (Public Summary Document, Application No. 1454, crizotinib, November 2017 MSAC meeting*). The PBAC advised that there was neither any new evidence nor any compelling justifications in the minor resubmission that was likely to necessitate any change to its previous interpretation of the clinical evidence. However, the PBAC considered that changes to the economic model in relation to the efficacy of the comparator and the comparative effectiveness of crizotinib resulted in a high but acceptable incremental cost-effectiveness ratio, at the price proposed in the minor resubmission. *http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1454-Public

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DEFERASIROX Tablet 90 mg Tablet 180 mg Tablet 360 mg Jadenu® Novartis Pharmaceuticals Australia Pty Ltd New listing (Minor Submission)	Chronic iron overload	To request Section 100 (Highly Specialised Drug) listings of a new form of deferasirox.	The PBAC recommended Section 100 (Highly Specialised Drugs Program) listing of deferasirox film coated tablets for the treatment of chronic iron overload due to disorders of haemopoiesis. The PBAC's recommendation for listing was based on its assessment that deferasirox film coated tablets were biocomparable, rather than bioequivalent, to deferasirox dispersible tablets and a cost-minimisation analysis between the film coated and dispersible tablets.
DOLUTEGRAVIR WITH RILPIVIRINE Tablet containing dolutegravir 50 mg with rilpivirine 25 mg Juluca® ViiV Healthcare Pty Ltd New listing (Major Submission)	Human immunodeficiency virus (HIV) infection	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection.	The PBAC recommended the listing of the combination drug dolutegravir with rilpivirine (Juluca®) for the treatment of HIV infection in patients who are virologically suppressed on current treatment, on a weighted price cost minimisation basis with alternative treatments. The PBAC considered the alternative treatments for the cost minimisation to be Stribild® or Eviplera® for most patients and Odefsey® or Genvoya® for patients with renal impairment who cannot use Stribild or Eviplera. The PBAC considered Juluca to be of similar effectiveness and safety to these alternative treatments
1) ERTUGLIFLOZIN WITH SITAGLIPTIN 2) ERTUGLIFLOZIN 3) ERTUGLIFLOZIN WITH METFORMIN 4) SITAGLIPTIN 5) SITAGLIPTIN WITH METFORMIN 1) Tablet containing 5 mg ertugliflozin with 100 mg sitagliptin (as phosphate monohydrate)	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for triple oral combination therapy of ertugliflozin and sitagliptin with metformin for the treatment of patients with type 2 diabetes mellitus (T2DM).	The PBAC recommended the Authority Required (STREAMLINED) listing of ertugliflozin with sitagliptin fixed dose combination (FDC) products for use in combination with metformin as triple oral therapy in patients with Type 2 diabetes mellitus. The recommendation was made on a cost-minimisation basis to dapagliflozin with saxagliptin and empagliflozin with linagliptin. The PBAC considered that the evidence presented in the submission supported a claim of non-inferior efficacy and safety for ertugliflozin with sitagliptin, compared to dapagliflozin with saxagliptin and empagliflozin with linagliptin, all in combination with metformin.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Tablet containing 15 mg ertugliflozin with 100 mg sitagliptin (as phosphate monohydrate) 2) Ertugliflozin Tablet 5 mg Ertugliflozin Tablet 15 mg 3) Tablet containing 2.5 mg ertugliflozin with 500 mg metformin hydrochloride Tablet containing 2.5 mg ertugliflozin with 1 g metformin hydrochloride Tablet containing 7.5 mg ertugliflozin with 500 mg metformin hydrochloride Tablet containing 7.5 mg ertugliflozin with 1 g metformin hydrochloride 4) Sitagliptin Tablet 25 mg (as phosphate monohydrate) Sitagliptin Tablet 50 mg (as phosphate monohydrate) Sitagliptin Tablet 100 mg (as phosphate monohydrate) 5) Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 500 mg metformin hydrochloride Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 850 mg metformin hydrochloride Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride Tablet (modified release) containing 50 mg sitagliptin (as			

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phosphate monohydrate) with 1000 mg metformin hydrochloride Tablet (modified release) containing 100 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride Steglujan® Steglatro® Segluromet® Januvia® Janumet® Janumet XR® Merck Sharp & Dohme (Australia) Pty Ltd			

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1) ERTUGLIFLOZIN 2) ERTUGLIFLOZIN with METFORMIN 1) Tablet containing 15 mg ertugliflozin 2) Tablet containing 7.5 mg ertugliflozin with 500 mg metformin hydrochloride; Tablet containing 7.5 mg ertugliflozin with 1 g metformin hydrochloride 1) Steglatro® 2) Segluromet® Merck Sharp & Dohme (Australia) Pty Limited New listing (Minor submission)	Type 2 diabetes mellitus (T2DM)	Resubmission to request an Authority Required (STREAMLINED) listing for higher strength formulations of ertugliflozin and ertugliflozin with metformin for dual oral combination therapy for patients with type 2 diabetes mellitus who are inadequately controlled with metformin or a sulfonylurea.	The PBAC recommended the addition of 15 mg ertugliflozin, 7.5 mg ertugliflozin with 500 mg metformin and 7.5 mg ertugliflozin with 1 g metformin to the PBS. The PBAC recalled the main concern from the previous submission was the absence of a positive TGA delegate's overview for the ertugliflozin 15 mg strength. The PBAC noted the re-submission presented a positive TGA delegate's overview and clinical justification for accepting the higher strength of ertugliflozin, however noted that there appeared to remain a limited clinical need for the higher strength. The PBAC was supportive of the requested Authority Required (STREAMLINED) listing for the 15 mg ertugliflozin for dual oral therapy with metformin or sulfonylurea, and ertugliflozin with metformin fixed dose combination products, for the treatment of Type 2 diabetes in patients inadequately controlled with metformin or a sulfonylurea.
EVEROLIMUS Tablet, dispersible, 2 mg Tablet, dispersible, 3 mg Tablet, dispersible, 5 mg Afinitor® Novartis Pharmaceuticals Australia Change to listing (Other)	Tuberous sclerosis complex	To request an Authority Required listing for the treatment of patients with refractory seizures associated with tuberous sclerosis complex in combination with other anti-epileptic medications.	The PBAC recommended the Authority Required listing of everolimus (in a dispersible tablet form) for the treatment of refractory seizures associated with tuberous sclerosis complex (TSC). The PBAC noted the high clinical need for a treatment for this condition and requested further work is undertaken with the sponsor to develop an appropriate restriction to give effect to its recommendation.

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FERRIC DERISOMALTOSE Injection 500 mg (iron) in 5 mL Monofer® Pfizer Australia Pty Ltd New listing (Major Submission)	Iron deficiency anaemia (IDA)	To request an unrestricted benefit listing.	The PBAC recommended the unrestricted listing of ferric derisomaltose for the treatment of iron deficiency anaemia when treatment with oral iron is ineffective or not tolerated. This recommendation was made on a cost-minimisation basis with the main comparator, ferric carboxymaltose. The equi-effective doses were 1 mg ferric derisomaltose: 1 mg ferric carboxymaltose.
GOLIMUMAB Injection 50 mg in 0.5 mL single use pre-filled syringe Injection 50 mg in 0.5 mL single use pre-filled pen Simponi® Simponi Smartject® Janssen Cilag Pty Ltd Change to listing (Major submission)	Active non-radiographic axial spondyloarthritis (nr-axSpA)	Resubmission to request an Authority Required listing for the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA).	The PBAC recommended extending the PBS-listing of golimumab to include an Authority Required (written) listing for the treatment of patients with non-radiographic axial spondyloarthritis (nr-axSpA). The PBAC was satisfied that golimumab provides, for some patients, a significant improvement in efficacy over conventional care. The PBAC considered that the cost-effectiveness of golimumab was acceptable at the price applied in the economic model. The PBAC considered that effective controls would be needed to ensure that cost-effective treatment was realised and to limit the financial costs to the PBS to the restricted patient group.

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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 Limited Change to recommended listing (Minor submission)	Attention deficit hyperactivity disorder (ADHD)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of attention deficit hyperactivity disorder (ADHD) as add-on therapy in patients who have an inadequate response to stimulant therapy.	The PBAC recommended the Authority Required (STREAMLINED) listing of guanfacine, as add-on therapy in conjunction with optimised stimulant therapy, for attention deficit hyperactivity disorder (ADHD) in patients experiencing residual moderate-to-severe ADHD symptoms. The PBAC recalled that at its July 2017 meeting it considered that guanfacine was of superior comparative effectiveness and inferior comparative safety compared to placebo in the add-on therapy setting requested in this resubmission. The PBAC considered the resubmission had addressed outstanding issues regarding the price and utilisation estimates, however recommended a risk share arrangement would be required to address residual uncertainties regarding the likely uptake and use of guanfacine.
GUSELKUMAB Injection 100 mg in 1 mL single use pre-filled syringe Tremfya® Janssen-Cilag Pty Ltd New listing (Minor submission)	Severe chronic plaque psoriasis	Resubmission to request an Authority Required listing for the treatment of severe chronic plaque psoriasis.	The PBAC recommended an Authority Required listing of guselkumab on a cost-minimisation basis against the lowest cost biological agent available for severe chronic plaque psoriasis (CPP). In making this recommendation, the PBAC accepted any of the current PBS listed bDMARDs for severe CPP could be an alternative therapy to guselkumab.

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HEPATITIS B SURFACE ANTIGEN RECOMBINANT VACCINE Injection 20 micrograms in 1 mL vial Engerix-B ® GlaxoSmithKline Australia Pty Ltd New listing (Minor Submission)	Hepatitis B virus infection	To request temporary National Immunisation Program (NIP) listing of Hepatitis B surface antigen recombinant vaccine, Engerix-B (adult formulation), for use in adolescents and adults due to a shortage of the NIP listed adult formulation of H-B-Vax II for the same indication and population.	The PBAC recommended that Engerix-B (adult formulation) be a designated vaccine for the purposes of Section 9B of the *National Health Act 1953* on a temporary basis for use in adolescents and adults until either the current shortage of H-B-Vax II (adult formulation, Seqirus Australia Pty Ltd) has been resolved, or 31 December 2019 (when shortage is predicted to end), whichever were to occur first. The PBAC considered that Engerix-B was sufficiently interchangeable with H-B-VAX II based on the advice of the Australian Technical Advisory Group on Immunisation, and noted that the temporary listing would be cost neutral. The PBAC considered that the temporary listing would ensure ongoing coverage for the catch up populations that are eligible for the vaccine under the NIP.
INSECT ALLERGEN EXTRACTS 1) Honey bee venom, injection set containing 550 micrograms with diluent 2) Paper wasp venom, injection set containing 550 micrograms 3) Yellow jacket venom, injection set containing 550 micrograms Hymenoptera Honey Bee Venom® Hymenoptera Paper Wasp Venom® Hymenoptera Yellow Jacket Venom® Stallergenes Australia Pty Ltd New Listing (Minor Submission)	Unrestricted	To request temporary listings for substitute products as alternatives for the currently listed bee venom, paper wasp venom and yellow jacket venom.	The PBAC recommended the temporary listing of Hymenoptera branded honey bee venom, paper wasp venom and yellow jacket venom to address the current shortage of PBS-listed insect allergen extracts.

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INSULIN GLARGINE Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 Semglee® Alphapharm Pty Ltd New listing (Minor Submission)	Unrestricted (indicated for diabetes mellitus)	To request an unrestricted benefit listing for this biosimilar brand for all indications for which the reference biologic is currently PBS listed.	The PBAC recommended the unrestricted listing the biosimilar brand of insulin glargine (Semglee®). The PBAC advised that, under Section 101(4AACD) of *the National Health Act, 1953*, the Semglee® and Lantus Solostar brands of insulin glargine injection device could be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution at the pharmacy level ('a' flagged). The PBAC considered that any differences in the devices could be safely managed by health care professionals in the course of regular patient education and counselling that is provided on the use of devices.
IXEKIZUMAB Injection 80 mg in 1 mL single dose pre-filled pen Injection 80 mg in 1 mL single dose pre-filled syringe Taltz® Eli Lilly Australia Pty Ltd Change to listing (Major submission)	Severe active psoriatic arthritis	To request an Authority Required listing for the treatment of severe active psoriatic arthritis.	The PBAC recommended the Authority Required listing of ixekizumab for the treatment of severe psoriatic arthritis on a cost-minimisation basis against the least costly biological Disease Modifying Anti-Rheumatic Drug (bDMARD). In making this recommendation, the PBAC accepted any of the current PBS listed bDMARDs for severe PsA could be an alternative therapy to ixekizumab.
LANREOTIDE Injection 120 mg (as acetate) in single dose pre-filled syringe. Somatuline® Autogel® Ipsen Pty Ltd Change to listing (Minor Submission)	Non-functional gastroentero-pancreatic neuroendocrine tumours (GEP-NETs).	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of non-functional GEP-NETs in adult patients with unresectable locally advanced or metastatic disease.	The PBAC recommended extending the listing of lanreotide Injection 120 mg (as acetate) in single dose pre-filled syringe to include the treatment of non-functional gastroenteropancreatic neuroendocrine tumours in adults with unresectable locally advanced or metastatic disease. The PBAC were satisfied that lanreotide would be sufficiently cost-effective at the sponsor's proposed price given the proposed Risk Sharing Arrangement, small patient population and high clinical need.

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LENVATINIB Capsule 4 mg (as mesilate) Capsule 10 mg (as mesilate) Lenvima® Eisai Australia Pty Ltd Change to listing (Minor Submission)	Locally advanced or metastatic differentiated thyroid cancer	To request a change to the maximum quantity for the current Authority Required (STREAMLINED) listing.	The PBAC recommended an amendment to the Authority Required (STREAMLINED) listing for lenvatinib (Lenvima®) for the treatment of locally advanced or metastatic differentiated thyroid cancer, to allow for prescribing of one pack of 10 mg and two packs of 4 mg capsules. The PBAC, noting the advice from the Department, considered that this amendment should occur by removing the administrative advice stating, “no increase in the maximum quantity or the number of units may be authorised” in the current lenvatinib restriction, rather than by the addition of new item codes. The PBAC noted that this would allow patients taking an 8 mg dose to access one months’ supply via an authority request.

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LUMACAFTOR with IVACAFTOR Tablet containing lumacaftor 200mg with ivacaftor 125 mg Tablet containing lumacaftor 100 mg with ivacaftor 125 mg Orkambi® Vertex Pharmaceuticals (Australia) Pty Ltd New listing (Two major submissions, one for 6 – 11 year olds and one for 12+ year olds)	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of cystic fibrosis in patients aged 6 years and over who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene.	The PBAC recommended the PBS listing of lumacaftor with ivacaftor (Orkambi®) for the treatment of all patients aged 6 years and over who are homozygous for the F508del mutation in the CFTR gene. The PBAC made its recommendation on the basis of 24 weeks of data in children aged 6 – 11 years and 96 weeks of data in patients aged 12 years and over. These data show treatment is beneficial for patients over these periods. However, as treatment for cystic fibrosis is life long, the PBAC, like the Therapeutic Goods Administration (TGA), has asked the sponsor collect longer term information on the effectiveness and safety of lumacaftor with ivacaftor. The PBAC considered it would be appropriate for the listing of lumacaftor with ivacaftor to occur under a Managed Access Program (MAP). The PBAC recommended that as part of the MAP, the sponsor be required to provide the PBAC with the results for the long term study (study 110) that it is currently conducting in 6 – 11 year olds, as well as a report for the post-market study the sponsor is undertaking in 6- 11 year olds. The MAP considered appropriate by the PBAC would provide for subsidy to be paid at the sponsor's asking price for an extended period to allow the sponsor to provide further data to satisfy the PBAC that the differences in the rates of decline in lung function and pulmonary exacerbations observed over a 96 week trial period are sustained over a longer time period of at least 4 years in real clinical practice. If, at the end of the initial period of the MAP, the sponsor's assumptions on rate of decline of lung function cannot be substantiated or can only be partially substantiated under the MAP, the price paid for lumacaftor with ivacaftor would reduce to a level consistent with the evidence provided to the PBAC. The PBAC noted that lumacaftor with ivacaftor has not been approved by the TGA for use in patients aged 2- 5 years.

JULY 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
MENINGOCOCCAL POLYSACCHARIDE SERO (GROUPS A, C, W-135 AND Y) OLIGOSACCHARIDE CONJUGATE VACCINE Injection 0.5mL combination pack Menveo® GlaxoSmithKline Australia Pty Ltd New listing (Major Submission)	Meningococcal disease	To request listing on the National Immunisation Program (NIP) for the immunisation of adolescents aged approximately 15 years of age (Year 9 or 10 students), with a catch-up program for school-aged adolescents/young adults aged up to and including 19 years, delivered through a combination of strategies including school-based delivery and via primary care providers.	The PBAC recommended that meningococcal serogroups A, C, W135 and Y oligosaccharides conjugate (MenACWY-CRM, Menveo®) vaccine be a designated vaccine for the purposes of Section 9B of the *National Health Act 1953*for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W135, and Y (MenA, MenC, MenW135 and MenY, respectively). The recommendation was for a single dose for adolescents as part of a school based immunisation program for year 10 students (aged 14-16) and via a catch-up program for a single dose for adolescents aged up to 19 years old. The PBAC noted that the sponsor of MenACWY-CRM chose not to present a cost-effectiveness analysis compared with 'no vaccine' (placebo) in this submission, hence the basis of the recommendation for MenACWY-CRM for adolescents is cost-minimisation with MenACWY-TT (Nimenrix®, recommended at the March 2018 PBAC meeting) for the same population. The equi-effective doses are 0.5 mL MenACWY-CRM and 0.5mL MenACWY-TT.
MESALAZINE Tablet 1 g (enteric coated) Salofalk® Orphan Australia Pty Ltd New listing (Minor Submission)	Ulcerative colitis; Crohn disease	To request an Authority Required (STREAMLINED) listing for a new strength of mesalazine for the treatment of ulcerative colitis and Crohn disease.	The PBAC recommended the Authority Required (STREAMLINED) listing of mesalazine 1 g enteric-coated tablets a for the treatment of ulcerative colitis and Crohn disease on a cost-minimisation basis against the oral formulation of mesalazine on the PBS with the lowest price per milligram of mesalazine and with the same restriction as the currently listed tablet forms of mesalazine.

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METHOTREXATE Injection 7.5 mg in 0.3 mL pre-filled syringe Injection 10 mg in 0.4 mL pre-filled syringe Injection 15 mg in 0.6 mL pre-filled syringe Injection 20 mg in 0.8 mL pre-filled syringe Injection 25 mg in 1 mL pre-filled syringe Methoblastin® PFS Pfizer Australia Pty Ltd New listing (Minor Submission)	Severe active rheumatoid arthritis; Severe psoriasis	To request an Authority Required (STREAMLINED) listing of a new pre-filled syringe form of methotrexate.	The PBAC recommended the Authority Required (STREAMLINED) listing of five new forms of subcutaneous methotrexate (7.5 mg/0.3 mL, 10 mg/0.4 mL, 15 mg/0.6 mL, 20 mg/0.8 mL, 25 mg/1 mL) for the same indications as the currently PBS listed brand of subcutaneous methotrexate, Trexject®. The PBAC advised, under Section 101(4AACD) of the *National Health Act 1953* that methotrexate 7.5 mg in 0.3 mL syringe and 7.5 mg in 0.15 mL syringe; methotrexate 10 mg in 0.4 mL syringe and 10 mg in 0.2 mL syringe; methotrexate 15 mg in 0.6 mL syringe and 15 mg in 0.3 mL syringe; methotrexate 20 mg in 0.8 mL syringe and 20 mg in 0.4 mL syringe; methotrexate 25 mL in 1 mL syringe and 25 mg in 0.5 mL syringe could be marked as equivalent ('a' flagged) in the Schedule of Pharmaceutical Benefits for the purposes of substitution at the point of dispensing.
MIDOSTAURIN Capsule 25 mg Rydapt® Novartis Pharmaceuticals Australia Pty Ltd New listing (Major submission)	Acute myeloid leukaemia (AML)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of midostaurin for the treatment of patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3) mutation positive acute myeloid leukaemia (AML).	The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required listing of midostaurin for the treatment of FMS-like tyrosine kinase-3 (FLT3) mutation positive acute myeloid leukaemia (AML). In reaching this outcome, the PBAC acknowledged the high unmet clinical need in the proposed PBS population and considered that midostaurin treatment improved outcomes in FLT3 positive AML patients. The PBAC was satisfied that the economic model presented in the resubmission addressed a majority of the concerns raised by the Committee at its November 2017 consideration of midostaurin. Taking into account all the evidence presented in the resubmission, and the reduced price across all treatment settings proposed in the pre-PBAC response, the PBAC considered that midostaurin was acceptably cost-effective at the price proposed by the resubmission, noting the unmet clinical need in patients with an uncommon disease with high rates of fatality. The PBAC advised that a risk sharing agreement be negotiated with the sponsor prior to PBS listing, to mitigate the risk of leakage outside the proposed PBS population.

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NIVOLUMAB and IPILIMUMAB nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL Opdivo® and Yervoy® Bristol-Myers Squibb Australia Pty Ltd New listing (Major submission)	Malignant melanoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the concurrent use of nivolumab and ipilimumab for the treatment of unresectable Stage III or Stage IV malignant melanoma.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy – Public and Private Hospital) Authority Required (STREAMLINED) listing of concurrent use of nivolumab and ipilimumab (NIVO+IPI) for the treatment of unresectable Stage III or Stage IV malignant melanoma in two treatment settings. One setting is first-line immunotherapy in patients with BRAF V600 mutation negative melanoma. The second setting is in patients with BRAF V600 mutation positive melanoma whose disease has progressed following treatment with a BRAF inhibitor. In making this recommendation, the PBAC considered the high unmet clinical need in an aggressive and debilitating malignancy and advised that NIVO+IPI resulted in a modest, yet meaningful, improvement in progression free survival for some patients compared to nivolumab monotherapy. The PBAC noted that the effect on quality of life and overall survival remained unknown and that the NIVO+IPI combination resulted in a higher adverse event rate compared to nivolumab monotherapy.
OBINUTUZUMAB Solution for I.V. infusion 1000 mg in 40 mL Gazyva® Roche Products Pty Ltd Change to listing (Minor Submission)	Chronic lymphocytic leukaemia (CLL)	To request that the current listings be changed to Authority Required (STREAMLINED).	The PBAC recommended changing the current Section 100 (Efficient Funding of Chemotherapy (EFC) Program) Authority Required (Written) listing for obinutuzumab to a Section100 EFC Authority Required (STREAMLINED) for treatment of CLL. The PBAC recalled that, at its March 2015 meeting, it recommended listing obinutuzumab on the PBS as a Written Authority to prevent usage outside of the restriction, with a view to reviewing the restriction level after two years when a more accurate estimation of the patient population would be possible. The PBAC was satisfied that a Streamlined Authority was appropriate based on: • Utilisation analysis by the Drug Utilisation Sub Committee Secretariat showing that the PBS usage of obinutuzumab over the first two years of listing was significantly lower than that predicted in the original submission; and • The recent listing of two other drugs on the PBS for patients with CLL who cannot tolerate a fludarabine based regimen (ofatumumab and rituximab).

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OCTREOTIDE Injection (modified release) 10 mg (as acetate), vial and diluent syringe Injection (modified release) 20 mg (as acetate), vial and diluent syringe Injection (modified release) 30 mg (as acetate), vial and diluent syringe Sandostatin LAR® Novartis Pharmaceuticals Australia Pty Ltd Change to listing (Minor Submission)	Functional carcinoid tumour; Acromegaly; Vasoactive intestinal peptide secreting tumour (VIPoma)	To request that the current listing supply arrangements be expanded to include Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listings.	The PBAC recommended the extension of the current listings for octreotide injection (modified release) 10 mg, 20 mg, 30 mg (as acetate), vial and diluent syringe from Section 100 Highly Specialised Drugs (HSD) program to a Section 100 HSD Community Access, Authority Required (STREAMLINED) for patients with acromegaly, functional carcinoid tumours and vasoactive intestinal peptide secreting tumours (VIPomas) under the conditions noted below. The PBAC recommended that the continuing phase of treatment be made available under Section 100 HSD program (Community Access), while the initial phase of treatment should remain unchanged under Section 100 – HSD program (Public and Private Hospitals).
PEMBROLIZUMAB Powder for injection 50 mg Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck, Sharp & Dohme (Australia) Pty Ltd Change to listing (Minor submission)	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as first line monotherapy in patients expressing PD-L1 for NSCLC.	The PBAC recommended listing pembrolizumab for the first-line treatment of patients with metastatic (Stage IV) non-small cell lung cancer (NSCLC), who have high expression of programmed cell death ligand 1 (PD-L1), defined as a tumour proportion score (TPS) of ≥50%. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of pembrolizumab was within an acceptable range based on a respecified economic model, and there was a sufficiently confident basis to estimate the overall net cost to the PBS in each year for eligible patients defined by the requested listing. The PBAC noted that the Medical Services Advisory Committee (MSAC) had foreshadowed its support for a new Medical Benefits Schedule (MBS) item for the immunohistochemistry testing of PD-L1 expression to help determine eligibility for PBS subsidised pembrolizumab (Public Summary Document, Application No. 1440.1).

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PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd Change to listing (Major submission)	Locally advanced or metastatic urothelial cancer (LA or mUC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of LA or mUC after the failure of a prior platinum-based chemotherapy.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy – Public and Private Hospital) Authority Required (STREAMLINED) listing of pembrolizumab for the second line treatment of locally advanced or metastatic urothelial cancer. In making this recommendation, the PBAC acknowledged the high clinical need for new treatments in urothelial cancer and the evidence from the pivotal clinical trial, KEYNOTE-045, which demonstrated improved overall survival for patients receiving pembrolizumab. The PBAC's recommendation for listing was based on, among other matters, it's assessment that the cost-effectiveness of pembrolizumab could be brought into an acceptable range with a reduced effective price.
SOFOSBUVIR WITH VELPATASVIR AND VOXILAPREVIR Tablet containing sofosbuvir 400 mg with velpatasvir 100 mg and voxilaprevir 100 mg Vosevi® Gilead Sciences Pty Ltd New listing	Chronic hepatitis C virus (HCV) infection	To request a General Schedule and Section 100 (Highly Specialised Drugs Program) listing for the treatment of HCV infection in adults who have failed treatment with an NS5A-based direct acting antiviral treatment regimen, regardless of genotype.	The PBAC recommended the listing of sofosbuvir with velpatasvir with voxilaprevir (SOF/VEL/VOX) for the treatment patients with chronic hepatitis C virus (HCV) infection, regardless of genotype, who have failed treatment with an NS5A-based treatment regimen on a cost minimisation basis with glecaprevir with pibrentasvir (GLE/PIB), under the same listing conditions as GLE/PIB.
SOMATROPIN Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) SciTropin A™ SciGen (Australia) Pty Ltd New listing (Minor Submission)	Growth disturbance due to insufficient secretion of pituitary growth hormone, or growth disturbance associated with gonadal dysgenesis (Turner syndrome) or chronic renal insufficiency	To request a Section 100 (Growth Hormone Programme) Authority Required listing of an additional strength of somatropin injection.	The PBAC recommended the re-listing of 5 mg (15 i.u.) in 1.5 mL form of somatropin under the SciTropin A brand in the Section 100 Growth Hormone Programme under the same conditions for which the Omnitrope® brand was listed. The PBAC noted that this brand of somatropin sought the same listing as the previously listed product, Omnitrope®, which is now re-marketed by a new sponsor under a new brand name, SciTropin A.

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TENOFOVIR ALAFENAMIDE WITH EMTRICITABINE AND BICTEGRAVIR Tablet containing tenofovir alafenamide 25 mg with emtricitabine 200 mg and bictegravir 50 mg Biktarvy® Gilead Sciences Pty Ltd New listing (Major Submission)	Human immunodeficiency virus (HIV) infection	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection.	The PBAC recommended the Authority Required (STREAMLINED) Section 100 (Community Access) listing of tenofovir alafenamide with emtricitabine and bictegravir (BFTAF) in a fixed dose combination tablet for the treatment of patients with human immunodeficiency virus (HIV) on a weighted price cost-minimisation basis with alternative treatments. The PBAC considered the alternative treatments for the cost minimisation to be Stribild® or Eviplera® for most patients and Genvoya® or Odefsey® for patients with renal impairment who cannot use Stribild or Eviplera. The PBAC considered BFTAF to be of similar effectiveness and safety to these alternative treatments.
TILDRAKIZUMAB Injection 100 mg in 1 mL single use pre-filled syringes Ilumya® Sun Pharma ANZ Pty Ltd New listing (Major Submission)	Severe chronic plaque psoriasis	To request an Authority Required listing for the treatment of patients with severe chronic plaque psoriasis.	The PBAC recommended the listing of tildrakizumab for the treatment of adult patients with severe chronic plaque psoriasis on the basis that the cost-effectiveness of tildrakizumab would be accepted if it were cost-minimised against the lowest cost bDMARD for this indication.
TOCILIZUMAB Injection 162 mg in 0.9 mL pre-filled pen Actemra® Subcutaneous Injection Roche Products Pty Ltd New listing (Minor Submission)	Severe active rheumatoid arthritis	To request an Authority Required listing of a new form of subcutaneous tocilizumab.	The PBAC recommended the Authority Required listing of a new form of subcutaneous tocilizumab (162 mg in 0.9 mL) delivered in an auto-injector for the treatment of severe active rheumatoid arthritis (RA) in adult patients. The PBAC advised that the new form of tocilizumab should not be considered equivalent for the purposes of substitution (‘a’ flagged in the Schedule) to the existing pre-filled syringe due to the differences in the administration techniques between the devices.

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TOLVAPTAN Pack containing 28 tablets 15 mg and 28 tablets 45 mg Pack containing 28 tablets 30 mg and 28 tablets 60 mg Pack containing 28 tablets 30 mg and 28 tablets 90 mg Jinarc® Otsuka Australia Pharmaceutical Pty Ltd New listing (Minor submission)	Autosomal dominant polycystic kidney disease (ADPKD)	Resubmission to request an Authority Required listing for the treatment of autosomal dominant polycystic kidney disease (ADPKD).	The PBAC recommended the Authority Required listing of tolvaptan in patients with autosomal dominant polycystic kidney disease (ADPKD). The PBAC was satisfied that for some patients, tolvaptan provides a small benefit although its effect on the prevention of end stage kidney disease (ESKD) is uncertain. The PBAC considered that whilst the modelled cost-effectiveness remained highly variable, the cost effectiveness of tolvaptan at the reduced price offered, in conjunction with proposed Risk Share Agreement, would be acceptable for patients with stage 2–3 chronic kidney disease (CKD) and rapid disease progression. The PBAC acknowledged the current and previously expressed significant public interest in the listing of tolvaptan in the AKPD population.
TRIFLURIDINE + TIPIRACIL Tablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride) Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride) LONSURF® Servier Laboratories (Australia) Pty Ltd New listing (Minor submission)	Metastatic colorectal cancer	Resubmission to request an Authority Required (STREAMLINED) listing for adult patients with metastatic colorectal cancer.	The PBAC recommended the Authority Required (STREAMLINED) listing of trifluridine with tipiracil for the treatment of patients with metastatic colorectal cancer who have been treated previously or are not considered suitable for current available therapies. The PBAC considered that in the context of limited treatment options in this disease setting, the small treatment benefit of trifluridine with tipiracil may be meaningful for some patients. The PBAC considered that the reduced price proposed in conjunction with the proposed Risk Share Agreement, were adequate to address the residual uncertainty around cost-effectiveness and budget impact.

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TRIGLYCERIDES MEDIUM CHAIN FORMULA Sachets containing oral powder 16 g, 30 (MCT Pro-Cal) MCT Pro-Cal Vitaflo Australia Pty Limited Change to listing (Minor Submission)	Chylous ascites; Chylothorax; Fat malabsorption; Hyperlipoproteinanaemia type 1; Long chain fatty acid oxidation disorders	To request a minor formulation change and new age restriction for the existing Authority Required (STREAMLINED) listing of MCT Pro-Cal.	The PBAC recommended the continued listing of triglycerides medium chain formula (MCT Pro-Cal®) with the minor change in nutritional profile and changes in the label description.
ZOLEDRONIC ACID Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL, 5 vials Claris Lifesciences Zoledronic Acid® Medsurge Healthcare Pty Ltd New Listings (Minor Submission)	Multiple myeloma	To request a temporary Section 100 Highly Specialised Drug Authority Required listing of zoledronic acid (Claris Lifesciences Zoledronic Acid®) on the Pharmaceutical Benefits Schedule (PBS) as an alternative to the currently listed zoledronic acid 4 mg/5 mL form (PBS items 6371H and 9653C), to address the current supply shortage issue.	The PBAC recommended the temporary listing of the Claris Lifesciences Zoledronic Acid® brand (4 mg/5 mL injection) to address the shortage of currently PBS-listed zoledronic acid brands.