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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ATEZOLIZUMAB Solution concentrate for I.V. infusion 1200 mg in 20 mL Tecentriq® Roche Products Pty Ltd New listing (Major Submission)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced (stage IIIB) or metastatic (stage IV) NSCLC with progression on or after prior chemotherapy.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy - Public and Private Hospital) Authority Required (STREAMLINED) listing for atezolizumab for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) in patients who have disease progression on or after prior platinum based chemotherapy on a cost-minimisation basis against nivolumab. In making this recommendation, the PBAC considered that atezolizumab was non-inferior in effectiveness and safety compared with nivolumab, which is currently listed on the PBS for this population. Consistent with the current listing of nivolumab, the PBAC advised that PBS-subsidised access to atezolizumab should not be conditional to the patient's PD-L1 expression status.
BALSALAZIDE Capsule containing balsalazide sodium 750 mg Colazide® Fresenius Kabi Australia Pty Ltd New listing (Minor Submission)	Ulcerative colitis	To request a new maximum quantity for the current Authority Required (STREAMLINED) listing.	The PBAC recommended an increase in the maximum quantity of balsalazide to 280 capsules. Although the PBAC considered there may be potential for wastage, it considered that this would be minimal for this chronic condition.
BRIVARACETAM Tablet 25 mg Table 50 mg Tablet 75 mg Tablet 100 mg Oral suspension 10 mg per mL, 300 mL Briviact® UCB Australia Pty Ltd New listing (Minor Submission)	Epilepsy	Resubmission to request Authority Required (STREAMLINED) listing for the treatment of intractable partial onset epileptic seizures.	The PBAC recommended an Authority Required (Streamlined) listing of brivaracetam for the treatment of intractable partial epileptic seizures on a cost-minimisation basis against lacosamide. The PBAC considered the positioning of brivaracetam as a third-line adjunctive therapy for use in the same population eligible for lacosamide and perampanel to be adequately supported, and that a claim that brivaracetam was non-inferior in effectiveness and safety compared with lacosamide was reasonable. The PBAC noted the financial risk associated with the use of brivaracetam in less refractory patients was mitigated by the pricing arrangements proposed by the sponsor and brivaracetam joining the existing Risk Sharing Arrangement for lacosamide and perampanel.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BUDESONIDE WITH EFORMOTEROL Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with eformoterol fumarate dihydrate 6 micrograms per dose, 120 doses Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with eformoterol fumarate dihydrate 12 micrograms per dose, 120 doses DuoResp® Spiromax® Teva Pharma Australia Pty Limited New listing (Minor Submission)	Asthma and chronic obstructive pulmonary disease (COPD)	Resubmission to request a Restricted Benefit listing for a new brand of budesonide with eformoterol (DuoResp® Spiromax®) for the treatment of patients with asthma and COPD aged 18 years and over.	The PBAC recommended the listing of a new brand of budesonide with eformoterol fumarate dehydrate for the treatment of asthma (DuoResp® 200/6 and 400/12 Spiromax®) and COPD (DuoResp® 400/12 Spiromax®). The PBAC noted that the delivery device for DuoResp® Spiromax® was different to the comparator (Symbicort® Turbuhaler®). The PBAC noted that for patients with asthma the DuoResp® Spiromax® brand does not cover all dose levels of the comparator for maintenance therapy due to the non-availability of the 100/6 strength. The PBAC considered that, as only a very small proportion of the market would potentially be affected by the omission of the 100/6 strength, the claimed ease of use and potential for improved adherence with a different delivery device outweighed any concerns regarding dose titration. The PBAC recommended that only the DuoResp® 400/12 Spiromax® strength be listed for COPD. The PBAC recommended that the DuoResp® 200/6 and 400/12 Spiromax® and the Symbicort® 200/6 and 400/12 Turbuhaler® could be marked as equivalent (i.e. “a” flagging) in the Schedule of Pharmaceutical Benefits. The PBAC considered that any differences in the devices could be managed in the course of the regular patient education and counselling on the use of the devices that is provided to patients by prescribers and pharmacists.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
CANAKINUMAB Powder for injection 150 mg with solvent Solution for injection 150 mg in 1 mL Ilaris® Novartis Pharmaceuticals Australia Pty Ltd Change to recommended listing (Major Submission)	Cryopyrin associated periodic syndromes (CAPS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe CAPS.	The PBAC recommended the listing of canakinumab for the treatment of moderate to severe cryopyrin-associated periodic syndromes (CAPS) under Section 100 – Highly Specialised Drugs Program on a cost-minimisation basis compared to anakinra. The PBAC considered that based on the evidence presented in the submission, the claim of similar efficacy and safety compared to anakinra was reasonable noting that CAPS is a rare condition with limited clinical data. The PBAC considered that canakinumab and anakinra should not be used in combination and hence recommended that the criterion of 'The treatment must be the sole PBS-subsidised biological medicine for this condition' should be added to the restriction for canakinumab and flowed-on to the restriction for anakinra for CAPS.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
1) DAPAGLIFLOZIN 2) DAPAGLIFLOZIN WITH METFORMIN 3) DAPAGLIFLOZIN WITH SAXAGLIPTIN 1) Tablet 10 mg (as propanediol monohydrate) 2) Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride 3) Tablet containing 10 mg dapagliflozin (as propanediol monohydrate) with 5 mg saxagliptin 1) Forziga® 2) Xigduo® XR 3) Qtern® AstraZeneca Pty Ltd New listing (Minor Submission)	Type 2 diabetes mellitus (T2DM)	Resubmission to request an Authority Required (STREAMLINED) listing for dapagliflozin in combination with a dipeptidyl peptidase 4 (DPP4) inhibitor and metformin for the treatment of T2DM.	The PBAC recommended the Authority Required (STREAMLINED) listing of dapagliflozin, dapagliflozin with metformin fixed dose combination (FDC) and dapagliflozin with saxagliptin FDC, for the use in triple oral therapy (DPP4 inhibitor + Sodium-glucose co-transporter-2 (SGLT2) inhibitor + metformin) in patients with T2DM on a cost-minimisation basis to empagliflozin with linagliptin. The equi-effective doses are empagliflozin 10 mg or 25 mg to dapagliflozin 10 mg, and linagliptin 5 mg to saxagliptin 5 mg.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DEFERIPRONE Tablet 1000 mg Ferriprox® Apotex Pty Ltd New listing (Minor Submission)	Iron overload	To request an Authority Required (STREAMLINED) listing of new form of deferiprone.	The PBAC recommended the Section 100 Highly Specialised Drugs, Authority Required(STREAMLINED) listing for a higher strength tablet (1000mg) of deferiprone for the treatment of transfusional iron overload associated with thalassaemia major.
DEXAMETHASONE Intravitreal injection 700 micrograms Ozurdex® Allergan Australia Pty Ltd Change to listing (Major Submission)	Non-infectious uveitis (inflammatory disease of the eye)	To request an Authority Required listing for the treatment of non-infectious uveitis affecting the posterior segment of the eye.	The PBAC recommended an Authority Required listing of dexamethasone implant for the treatment of non-infectious posterior segment uveitis where systemic therapy or further intensification of systemic therapy is not required or contraindicated, on the basis of superior effectiveness and inferior safety compared with standard of care. The submission presented a direct comparison of dexamethasone implant versus placebo or surgery in which patients received the procedure but not the medicine ('placebo treatment'), based on one randomised controlled trial in patients with non-infectious posterior segment uveitis. The PBAC considered that the evidence demonstrated that dexamethasone implant improved patient vision when compared to placebo treatment. The PBAC accepted the claim that dexamethasone implant is inferior in terms of safety when compared with the placebo treatment but had a manageable safety profile. The PBAC recognised an unmet clinical need for this therapy as there are no reimbursed local therapies for the treatment of non-infectious posterior segment uveitis.
DULAGLUTIDE Injection 1.5 mg in 0.5 mL single does pre-filled pen Trulicity® Eli Lilly Australia Pty Ltd Change to listing (Major Submission)	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for use in combination with metformin or metformin and a sulfonylurea, for the treatment of T2DM.	The PBAC recommended the listing of dulaglutide for the treatment of type 2 diabetes mellitus as dual or triple therapy in combination with metformin and/or a sulfonylurea. The PBAC considered, amongst other matters, that dulaglutide would be acceptably cost-effective if it were cost minimised against exenatide.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
EMPAGLIFLOZIN WITH LINAGLIPTIN Tablet containing 10 mg empagliflozin with 5 mg linagliptin Tablet containing 25 mg empagliflozin with 5 mg linagliptin Glyxambi® Boehringer Ingelheim Pty Limited New listing (Major Submission)	Type 2 diabetes mellitus (T2DM)	Resubmission to request an Authority Required (STREAMLINED) listing for use in combination with metformin for the treatment of T2DM.	The PBAC recommended the listing of empagliflozin with linagliptin for use in combination with metformin for the treatment of type 2 diabetes. However, the PBAC did not recommended the listing of empagliflozin with linagliptin for the treatment of patients with type 2 diabetes and mild to moderate renal impairment because it was not sufficiently supported by the data presented in the submission. In a triple oral therapy context (dipeptidyl peptidase 4 (DPP4) inhibitor + Sodium-glucose co-transporter-2 (SGLT2) inhibitor + metformin), the PBAC noted that although the data presented in the submission indicated the empagliflozin with linagliptin was non-inferior to insulin glargine and exenatide, and dapagliflozin with saxagliptin, all in combination with metformin, the incremental benefit of adding a third agent was smaller in magnitude than the benefit observed when adding either agent in the dual therapy setting. However, the PBAC considered that the price proposed by the sponsor accounted for this reduction of benefit in triple oral therapy, and any remaining uncertainty.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
1) EMPAGLIFLOZIN 2) EMPAGLIFLOZIN WITH METFORMIN 3) LINAGLIPTIN 4) LINAGLIPTIN WITH METFORMIN 1) Tablet 10mg Tablet 25 mg 2) Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride 3) Tablet 5 mg 4) Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride Tablet containing 2.5 mg linagliptin with 1 g metformin hydrochloride Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride 1) Jardiance® 2) Jardiamet® 3) Trajenta® 4) Trajentamet® Boehringer Ingelheim Pty Limited Change to listing (Minor Submission)	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) for the use in triple oral therapy regimen of empagliflozin and linagliptin with metformin for the treatment of T2DM.	The PBAC recommended the Authority Required (STREAMLINED) listing of empagliflozin, linagliptin and their respective fixed dose combination products with metformin, for use in triple oral therapy (empagliflozin + linagliptin + metformin) in patients with T2DM on the basis of acceptable cost-effectiveness demonstrated by the concurrent major submission for empagliflozin and linagliptin fixed dose combination.

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
FOLLITROPIN DELTA Solution for injection 12 micrograms per 0.36 mL pre-filled cartridge Solution for injection 36 micrograms per 1.08 mL pre-filled cartridge Solution for injection 72 micrograms per 2.16 mL pre-filled cartridge Rekovelle® Ferring Pharmaceuticals Pty Ltd New listing (Major Submission)	Assisted reproductive technology (ART)	To request a Section 100 (IVF) Authority Required (STREAMLINED) listing for controlled ovarian stimulation in ART.	The PBAC recommended the listing of follitropin delta under a section 100 special arrangement for controlled ovarian stimulation in patients undergoing assisted reproductive technologies, on a cost-minimisation basis against follitropin alfa with equi-effective dosing based on 1,896 international units of follitropin alfa to 93.6 micrograms of follitropin delta.
GLECAPREVIR WITH PIBRENTASVIR Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir Maviret® AbbVie Pty Ltd New listing (Minor Submission)	Chronic hepatitis C virus (HCV) infection	To request an Authority Required General Schedule and Section 100 (Highly Specialised Drug) listing for chronic HCV infection in patients who have failed prior treatment with an NS5A inhibitor.	The PBAC, recalling it had deferred the major submission from July 2017 pending the provision of the relevant TGA delegate's overview - which has now been received, recommended the Authority Required General Schedule and Section 100 listing of glecaprevir with pibrentasvir for the treatment of chronic hepatitis C infection for treatment naïve and treatment experienced patients (including those with prior NS5A treatment) with genotypes 1-6, with or without cirrhosis. The PBAC's was of the view that that the cost-effectiveness of glecaprevir with pibrentasvir is acceptable if it were cost-minimised against the relevant lowest priced alternative regimen in the General Statement for Drugs for the Treatment of Hepatitis C. The PBAC also recommended that glecaprevir with pibrentasvir fixed dose combination enter the Risk Sharing Arrangement currently in place for other drugs used for the treatment of HCV infection.

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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 16 g, 60 (PKU Build 10) Sachets containing oral powder 32g, 30 (PKU Build 20) PKU Build 10® PKU Build 20® Cortex Health Pty Ltd New listing (Minor Submission)	Phenylketonuria	To request a Restricted Benefit listing for the dietary management of phenylketonuria.	The PBAC recommended the listing of PKU Build 10® and PKU Build 20® as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis against the nominated comparators Camino Pro® Bettermilk and PKU Bettermilk Lite® at an equivalent price per gram of protein equivalent.
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Bars 81 g, 14 (Tylactin Complete) Tylactin Complete® Cortex Health New listing (Minor Submission)	Tyrosinaemia	To request a Restricted Benefit Listing for the dietary management of tyrosinaemia.	The PBAC recommended the listing of Tylactin Complete® as a Restricted Benefit for the dietary management of tyrosinaemia on a cost-minimisation basis against the comparator Tylactin RTD® at an equivalent price per gram of protein equivalent.

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GOLIMUMAB Injection 100 mg in 1 mL single use pre-filled syringe Simponi® Janssen-Cilag Pty Ltd Change to listing (Major Submission)	Moderate to severe ulcerative colitis	To request an Authority Required listing for the treatment of adult patients with moderate to severe ulcerative colitis, who have had an inadequate response to conventional therapy.	The PBAC recommended the Authority Required listing of golimumab for the treatment of moderate to severe ulcerative colitis, on a cost-minimisation basis against the least expensive PBS listed biological disease modifying anti-rheumatic drug for this condition. The PBAC accepted that golimumab was non-inferior in efficacy and safety to vedolizumab and adalimumab in both induction and maintenance therapy; and inferior to infliximab for efficacy for induction, but non-inferior to infliximab for safety and for efficacy in maintenance therapy.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
INFLIXIMAB Powder for I.V. infusion 100 mg Renflexis® Merck Sharp & Dohme (Australia) Pty Ltd Change to listing (Minor Submission)	Multiple indications	To request that the current listings for Renflexis be changed to Authority Required (STREAMLINED) for patients continuing on treatment or switching from the reference biologic or from another bDMARD.	The PBAC advised that there are no clinical or other concerns about appropriate use of medicines if the policy to lower the authority requirement for only the biosimilar brands of infliximab is adopted providing the recommendations below are followed. The PBAC recommended that all initial treatment restrictions for infliximab, including those for new patients, patients changing treatment and recommencing treatment, remain as Authority Required (in writing). The PBAC advised that the current restriction for acute severe ulcerative colitis remain unchanged for public hospitals as it is already an Authority Required (STREAMLINED) within the Section 100 Highly Specialised Drugs program. This will ensure the medicine will continue to be targeted at the group where cost-effectiveness has been accepted. The PBAC did not recommend lowering the category of authority for the initial eligibility criteria (restriction) for patients changing to or recommencing treatment with infliximab, or for the restrictions that apply to continuing treatment with infliximab. PBAC considered that changing the restrictions, as proposed by the sponsor, for these treatment phases to Authority required (STREAMLINED) was likely to result in use outside the intended PBS population to a wider population, such as patients who do not demonstrate the extent of response required for continuing treatment and use in patients with less severe disease. The PBAC recommended that the continuing restrictions for infliximab be split into first continuing and subsequent continuing restrictions. The PBAC recommended that the first continuing restrictions be Authority Required (in writing), retaining the response to treatment criteria that currently exists in the continuing restrictions for infliximab. The PBAC recommended that the subsequent continuing restrictions be Authority Required (STREAMLINED) restrictions. The PBAC recommended that subsequent continuing restrictions for infliximab retain the requirement for patients to be responding to treatment. The PBAC confirmed its previous recommendation regarding 'a' flagging which is intended to support all brands of infliximab. The PBAC noted the request for a change to prescribing software to give preference to Renflexis® for infliximab naïve patients. The PBAC did not have any concerns about encouraging prescribing of a biosimilar brand for treatment naïve patients.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
INSULIN LISPRO Injections (human analogue), cartridges, 200 units per mL, 3 mL, 5 Humalog® U200 Kwikpen® Eli Lilly Australia Pty Ltd New listing (Minor Submission)	Diabetes mellitus	To request an unrestricted listing of a new form of insulin lispro.	The PBAC recommended the listing of the new strength of insulin lispro Humalog U200 for the treatment of type 1 and 2 diabetes mellitus. Listing was recommended on a cost minimisation basis per unit of insulin with insulin lispro Humalog U100.
LANREOTIDE Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel® Ipsen Pty Ltd Change to listing (Minor Submission)	Acromegaly and functional carcinoid tumour	To request that the current listing supply arrangements be changed from Section 100 (Highly Specialised Drugs Program) to Section 100 (Highly Specialised Drugs Program - Community Access).	The PBAC recommended to extend the current listing for lanreotide acetate 60 mg/0.5 mL, 90 mg/0.5 mL and 120 mg/0.5 mL pre-filled syringes, Somatuline Autogel pre-filled syringe from Section 100 Highly Specialised Drugs program (HSD) to a Section 100 HSD Community Access, Authority Required (STREAMLINED) for patients with acromegaly and functional carcinoid tumour under the conditions noted below. The PBAC recommended that the continuing phase of treatment be made available under Section 100 - Highly Specialised Drugs Program (Community Access), while the initial phase of treatment should remain unchanged under Section 100 – Highly Specialised Drugs Program (Public and Private Hospitals).
LENALIDOMIDE Capsule, 5 mg, 10 mg, 15 mg, 25 mg Revlimid® Celgene Change to listing (Minor Submission)	Relapsed/refractory multiple myeloma (RRMM)	To seek the PBAC's advice on the extension of the listing for lenalidomide to remove the requirement for thalidomide trial prior to lenalidomide use, and to allow retreatment with lenalidomide in RRMM.	The committee advised, out of session, that listing for lenalidomide should be modified to remove the requirement for a thalidomide trial prior to lenalidomide use, and to allow retreatment with lenalidomide in RRMM.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
MEPOLIZUMAB Powder for injection 100 mg Nucala® GlaxoSmithKline Australia Pty Ltd Change to listing (Minor Submission)	Uncontrolled severe eosinophilic asthma	To request an extension to the duration that eosinophil test results are considered valid to support initial access to PBS-subsidised mepolizumab.	The PBAC recommended extending the eosinophil blood test validity period from 6 weeks to 12 months in the mepolizumab listing to align with the omalizumab listing for uncontrolled severe allergic asthma. The PBAC noted that this would allow improved access to mepolizumab treatment by reducing the time and administrative burden for patients and clinicians.
PEGINTERFERON ALFA-2A Injection 135 micrograms in 0.5 mL single use pre filled syringe Injection 180 micrograms in 0.5 mL single use pre-filled syringe Pegasys® Roche Products Pty Ltd New listing (Minor Submission)	Myeloproliferative neoplasms (MPN)	To request the current Section 100 (Highly Specialised Drugs) Authority Required (STREAMLINED) listing to be changed to an unrestricted listing.	The PBAC recommended the change in listing for peginterferon alfa-2a from Authority Required (STREAMLINED) and Authority Required to Unrestricted, on the basis of the proposed price reduction and risk sharing arrangements.
POMALIDOMIDE Capsule 3 mg Capsule 4 mg Pomalyst® Celgene Pty Ltd Change to listing (Minor Submission)	Relapsed/refractory multiple myeloma (RRMM)	Resubmission to request an amendment to the Section 100 (Highly Specialised Drug) listing to include patients with relapsed or refractory multiple myeloma who are contraindicated or intolerant to bortezomib and/or lenalidomide.	The PBAC recommended extending the current restriction for pomalidomide to include the treatment of patients who are contraindicated to, or who have experienced severe intolerance to lenalidomide and/or bortezomib for RRMM. The PBAC considered that the proposed risk sharing arrangements for the extended population would render pomalidomide acceptably cost-effective in this setting.

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PONATINIB Tablet 15 mg (as hydrochloride) Tablet 45 mg (as hydrochloride) Iclusig® Specialised Therapeutics Australia Change to listing (Minor Submission)	Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukaemia (ALL)	To request a change to the current Authority Required listing for the treatment Philadelphia chromosome positive ALL to remove the requirement to have a T315I mutation.	The PBAC recommended amending the current ponatinib restriction for relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) to include all patients, regardless of T315I mutation status, who have failed or are intolerant to dasatinib noting that the patient population of the requested extension is small. In making its recommendation, the PBAC also considered that the ponatinib and dasatinib restrictions for Ph+ ALL should be updated to align with current treatment guidelines.
PRALATREXATE Solution for I.V. infusion 20 mg in 1 mL Folotyn® Mundipharma Pty Ltd New listing (Minor Submission)	Peripheral T-Cell Lymphoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with peripheral T-cell lymphoma who are refractory to, or have relapsed following, first line chemotherapy.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy - Public and Private Hospital) Authority Required listing for pralatrexate 20mg/mL vials for treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL), on the basis that the proposed pricing arrangements for pralatrexate adequately addressed the uncertainty with the cost-effectiveness estimates, noting that pralatrexate will fulfil a clinical need.
RADIUM (223Ra) Injection containing radium (223Ra) dichloride 6.6 MBq in 6 mL vial Xofigo® Bayer Australia Ltd New listing (Minor Submission)	Metastatic castrate resistant prostate cancer (mCRPC)	To request the Authority Required listing for the treatment of mCRPC.	The PBAC recommended the listing of Radium 223Ra dichloride (Xofigo®), for the treatment of castration resistant metastatic carcinoma of the prostate on a cost-minimisation basis with abiraterone. The PBAC considered the Medical Services Advisory Committee's (MSAC) prior (April 2014) consideration and recommendation to list 223Ra on the MBS to in making its recommendation. The PBAC considered 223Ra should join the same Risk Sharing Arrangement as abiraterone and enzalutamide.

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RALTEGRAVIR Tablet 600 mg (as potassium) Isentress HD® Merck, Sharp and Dohme (Australia) 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 in combination with other antiretroviral agents.	The PBAC recommended, out of session, the Section 100 (Highly Specialised Drugs Program – Community Access), Authority Required (STREAMLINED) listing of raltegravir 600 mg tablets (as 1,200 mg once daily) for the treatment of Human Immunodeficiency Virus (HIV) infection, in combination with other anti-retroviral agents, on a cost minimisation basis with raltegravir 400 mg tablets twice daily. The PBAC recalled it had deferred the major submission from July 2017 pending the TGA Delegate's Proposed Regulatory Action.
SEVELAMER Powder for oral liquid 2.4 g (as carbonate) Renvela® Sanofi-Aventis Australia Pty Ltd New listing (Minor Submission)	Hyperphosphataemia in patients with chronic kidney disease	To request an Authority Required (STREAMLINED) listing of new form of sevelamer.	The PBAC recommended the General Schedule and Section 100 (Highly Specialised Drugs Program – Public and Private Hospital) Authority Required listing of sevelamer carbonate, as powder for suspension, for hyperphosphataemia in patients undergoing dialysis for chronic kidney disease. The PBAC noted that the expected average dose of the powder is 6 g per day but the 2.4 g pack when taken three times daily results in 7.2 g of sevelamer carbonate, an excess of 1.2 g per day per patient. Therefore, while the PBAC considered that the PBS listing of this formulation could potentially reduce the pill burden for these patients, in making this recommendation the PBAC advised the Minister that a lower price for sevelamer carbonate should be negotiated to take into account the Committee's concerns regarding use of higher doses and/or wastage upon administration of this strength of sevelamer carbonate.
SONIDEGIB Capsule 200 mg Odomzo® Sun Pharma Limited New listing (Major Submission)	Basal cell carcinoma (BCC)	To request an Authority Required listing for the treatment of patients with metastatic or locally advanced BCC who are not amenable to curative surgery or radiation therapy.	The PBAC recommended sonidegib as an Authority Required (in writing) listing for the treatment of metastatic or locally advanced BCC inappropriate for surgery and curative radiotherapy, on a cost-minimisation basis against vismodegib. In making this recommendation, the PBAC noted the relatively small population of patients with metastatic or locally advanced BCC who are inappropriate for surgery and curative radiotherapy and considered that there was a clinical role for an additional therapy. The PBAC noted that the submission was based on a naïve indirect comparison of non-randomised studies, and that the comparison was not robust due to low patient numbers in the sonidegib BOLT study and transitivity issues across the studies. However, given the patient population, the PBAC considered the clinical claims of non-inferior efficacy and non-inferior safety to vismodegib were adequately supported.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
TETRACOSACTRIN Compound depot injection 1 mg in 1 mL Synacthen® Depot 1 mg/1 mL Link Medical Products Pty Ltd Change to listing (Minor Submission)	Hypsarrhythmia and/or infantile spasms	To request the current unrestricted listing be changed to Restricted Benefit for the treatment of hypsarrythmia and/or infantile spasms.	The PBAC recommended the amendment of the current unrestricted benefit to a Restricted Benefit for use in patients with hypsarrhythmia and/or infantile spasms, noting this is a small patient group.
TIOTROPIUM BROMIDE WITH OLODATEROL HYDROCHLORIDE solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses Spiolto® Respimat®, Boehringer Ingelheim Pty Limited Change to listing (Minor Submission)	Asthma and chronic obstructive pulmonary disease (COPD)	To request a change to the current Authority Required (STREAMLINED) listing for tiotropium with olodaterol fixed dose combination (FDC) to allow patients who have symptoms that persist despite regular bronchodilator treatment with either a long acting muscarinic antagonist (LAMA) or long acting beta-2 agonist (LABA) to move straight to the FDC, in addition to those stabilised on a combination of a LAMA and LABA treatment.	The PBAC recommended the requested change to the Authority Required (STREAMLINED) listing for tiotropium bromide with olodaterol fixed dose combination (FDC) to allow patients who have persistent chronic obstructive pulmonary disease (COPD) symptoms despite regular monotherapy with a long acting muscarinic antagonist (LAMA) or long acting beta-2 agonist (LABA) to move straight to the FDC. The PBAC also noted that there are three other LAMA/LABA FDC currently listed on the PBS (aclidinium with eformoterol, indacaterol with glycopyrronium and umeclidinium with vilanterol), where the individual components are not available separately on the PBS. The PBAC considered that the change to the existing listing of tiotropium with olodaterol should also apply to these other LAMA/LABA FDCs.

NOVEMBER 2017 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
VARENICLINE Tablet 1 mg (as tartrate) Champix® Pfizer Autralia Pty Ltd Change to listing (Minor Submission)	Nicotine dependence	To request amendment on the Authority Required (STREAMLINED) listing for the treatment of nicotine dependence to enable access for patients who commence treatment in hospital.	The PBAC recommended the amendment to the continuing treatment listing of varenicline to include patients commencing therapy as hospital inpatients.
VENETOCLAX Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd Change to recommended listing (Minor Submission)	Relapsed/refractory chronic lymphoid leukaemia (CLL)	To request that the PBAC review the circumstances of listing recommended at its July 2017 meeting.	The PBAC reaffirmed its July 2017 recommendation that venetoclax be subsidised through the PBS for the treatment of relapsed or refractory chronic lymphocytic leukaemia in patients who have failed a kinase inhibitor, without necessarily requiring evidence that these patients have a 17p deletion. The PBAC recommended that venetoclax be listed as Authority Required (in writing) for initial treatment and as Authority Required (telephone) for continuing treatment. The PBAC recalled that it had recommended venetoclax in July 2017 on the basis of limited evidence in order to facilitate early patient access to this medicine.

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
1. VILDAGLIPTIN 2. VILDAGLIPTIN WITH METFORMIN 1. Tablet 50 mg 2. Tablet containing 50 mg vilgagliptin with 500 mg metformin hydrochloride Tablet containing 50 mg vilgagliptin with 850 mg metformin hydrochloride Tablet containing 50 mg vilgagliptin with 1000 mg metformin hydrochloride 1. Galvus® 2. Galvumet® Novartis Pharmaceuticals Australia Pty Ltd Change to listing (Major Submission)	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for use in combination with insulin for the treatment of patients with T2DM.	The PBAC recommended the Authority Required (streamlined) listing of vildagliptin and vildagliptin with metformin fixed dose combination (FDC) for use in combination with insulin.
VISMODEGIB Capsule, 150 mg, ERIVEDGE® Roche Products Pty Ltd. Change to listing (Minor Submission)	Basal cell carcinoma (BCC)	To request changes to the current initial and continuing restrictions of vismodegib to relax the requirement of a letter from a surgically qualified clinician and/or a radiation oncologist for patients with metastatic basal cell carcinoma.	The PBAC recommended, out of session, the change in listing for both initial and continuing treatment with vismodegib to remove the requirement for written confirmation from a surgeon AND radiation oncologist in patients with metastatic BCC disease.