PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2014 PBAC MEETING

Closing date for consumer comments 8 October 2014

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or the National Immunisation Program.

The PBAC agenda consists of the following:
1 Minutes of Previous Meeting
2 Chairman's report (verbal)
3 Matters arising from the minutes
4 Matters arising/outstanding
5 New drug applications
6 Requests for changes to listings
7 Resubmissions
8 Pricing Matters
9 Matters relating to PBS review
10 Subcommittee and Working Party reports
11 Other business
12 Correspondence
13 Further information
14 Late papers
15 Tabled papers

Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and re-submissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.

Pharmaceutical benefits listed in the Schedule fall into three broad categories:
Unrestricted benefits – have no restrictions on their therapeutic uses;
Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and
Authority required benefits – Authority required benefits fall into two categories:

- *Authority required benefits* require prior approval from Medicare Australia or the DVA (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Submissions are categorised broadly as major or minor:

- *Major:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
- *Minor:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.

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Submission type *(new listing, change to listing)*	**Drug Name, form(s), strength(s) and Sponsor** *(Drug name, form, strength, Trade name®, Sponsor)*	**Drug Type and Use** *(What is the drug used to treat?)*	**Listing requested by Sponsor / Purpose of Submission** *(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased*
Change to listing (Major submission)	ADALIMUMAB 20 mg/0.4 mL injection, 2 x 0.4 mL syringes 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges 40 mg/0.8 mL injection, 6 x 0.8 mL syringes Humira® AbbVie Pty Ltd	Paediatric Crohn's Disease	Authority Required listing for the treatment of paediatric Crohn disease in patients who meet certain criteria.
Change to listing (Major submission)	AFLIBERCEPT 4 mg/0.1 mL injection, 1 x 0.1 mL vial 4 mg/0.1 mL injection, 1 x 0.90 mL syringe Eylea® Bayer Australia Ltd	Diabetic Macular Oedema	Authority Required listing for the treatment of diabetic macular oedema.
Change to listing (Major submission)	AFLIBERCEPT 2 mg/0.05 mL injection, 1 x 0.05 mL vial 2 mg/0.05 mL injection, 1 x 0.05 mL syringe Eylea® Bayer Australia Ltd	Macular Oedema secondary to central retinal vein occlusion	Authority Required listing for the treatment of central retinal vein occlusion.

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Change to recommended listing (Minor submission)	ALEMTUZUMAB alemtuzumab 10 mg/mL injection, 1 x 2 mL vial Lemtrada® Genzyme (A Sanofi company) Pty Ltd	Multiple sclerosis	Amend the July 2014 PBAC recommendation to list alemtuzumab on a cost-minimisation basis with natalizumab and fingolimod with regards to the claimed dosing durability.
Change to listing (Minor submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 29 g sachets, TYR Anamix Junior® Nutricia Australia Pty Ltd	Medicinal food	To advise of an upgrade in the nutritional formula, flavour and packaging change from 29 g sachets to 36 g sachets.
Change to listing (Minor submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID 30 x 36 g sachets, MSUD Anamix® Junior Nutricia Australia Pty Ltd	Medicinal food	To advise of a minor change to the nutritional information of MSUD Anamix Junior.
Change to listing (Minor submission)	AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE 30 x 36 g sachets, PKU Anamix® Junior Nutricia Australia Pty Ltd	Medicinal food	To advise of a minor change to the nutritional information of PKU Anamix Junior.

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New listing (Minor submission)	AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE PKU Air Vitaflo Australia Pty Ltd	Medicinal food	Restricted benefit for phenylketonuria.
New listing (Major submission)	ANAKINRA 100 mg/0.67 mL, 28 x 0.67 mL syringes Kineret® A.Menarini Australia Pty Ltd	Cryopyrin Associated Periodic Syndromes	Section 100 Authority Required listing for the treatment of cryopyrin-associated periodic syndromes.
New listing (Minor submission)	APOMORPHINE HYDROCHLORIDE 10 mg /1 mL injection: 5 x 1 mL ampoules, Apomine® Hospira Pty Ltd	Parkinson disease	Section 100 Authority Required listing of a lower strength for the management of advanced Parkinson disease.
New listing (Major submission)	AXITINIB 1 mg tablet, 28 5 mg tablet, 28 Inlyta® Pfizer Australia Pty Ltd	Renal cell carcinoma	Authority Required listing for the treatment of Stage IV clear cell variant renal cell carcinoma in patients meeting certain criteria.
New listing (Minor submission)	BUPRENORPHINE + NALOXONE 4 mg/1 mg film: sublingual, 28 films 12 mg/3 mg film: sublingual, 28 films Suboxone® Sublingual film Reckitt Benckiser Pty Ltd	Opiate Dependence	Section 100 (Opiate Dependence Treatment Program) listing of two new strengths of buprenorphine + naloxone sublingual film.

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Change to listing (Major submission)	CERTOLIZUMAB PEGOL 200 mg/mL injection, 2 x 1 mL syringes Cimzia® UCB Australia Pty Ltd	Psoriatic arthritis	Authority Required listing for the treatment of patients with severe active psoriatic arthritis who meet certain criteria.
Change to listing (Major submission)	CETUXIMAB 100 mg/20 mL injection, 1 x 20 mL vial 500 mg/100 mL injection, 1 x 100 mL vial Erbitux® Merck Serono Australia Pty Ltd	Colorectal cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first line treatment of metastatic colorectal cancer in patients who meet certain criteria.
Change to listing (Major submission) WITHDRAWN	CINACALCET 30 mg tablet, 28 60 mg tablet, 28 90 mg tablet, 28 Sensipar® Amgen Australia Pty Ltd	Hyperparathyroidism	Amend the existing restriction to target patients with chronic kidney disease who are at high risk of cardiovascular events.
New listing (Minor submission)	COAL TAR PREPARED coal tar prepared, 2% (20 mg/g), foam aerosol, 100 g, Scytera® Foam Dr Reddy's Laboratories Australia Pty Ltd	Psoriasis	Unrestricted benefit listing.

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New listing (Minor submission)	CRIZOTINIB, capsules, 200 mg and 250 mg, Xalkori® Pfizer Australia Pty Ltd	Non-small cell lung cancer	To address key issues raised in the March 2014 PBAC deferral of crizotinib for the treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer.
Change to listing (Major submission) WITHDRAWN	DAPAGLIFLOZIN 10 mg tablet, 28 Forxiga® AstraZeneca Pty Ltd	Diabetes mellitus type 2	Amend the current Authority Required restriction to be the same as that applying to the dipeptidyl peptidase 4 inhibitors (gliptins).
Change to listing (Major submission)	DAPAGLIFLOZIN 10 mg tablet, 28 Forxiga® AstraZeneca Pty Ltd	Diabetes mellitus type 2	Extend the current Authority Required listing to include the treatment of diabetes mellitus type 2, in combination with insulin, in patients who meet certain criteria.
Change to listing (Major submission)	DIPHTHERIA + TETANUS + ACELLULAR PERTUSSIS (dTPa) VACCINE Infanrix® GlaxoSmithKline Australia Pty Ltd	Immunisation against pertussis	To request the inclusion of an additional booster dose of DTPa on the National Immunisation Program (NIP) at 18 months of age.
New listing (Major submission)	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30 Triumeq® ViiV Healthcare Pty Ltd	HIV Infection	Section 100 Authority Required listing for the treatment HIV infection in patients meeting certain criteria.

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New listing (Major submission)	ELOSULFASE ALFA 5 mg/5 mL injection, 5 mL vial Vimizim® Biomarin Pharmaceuticals Australia Pty Ltd	Mucopolysaccharidosis type IVA	Section 100 Authority Required listing for the treatment of mucopolysaccharidosis type IVA in patients who meet certain criteria.
Change to listing (Minor submission)	ELTROMBOPAG, tablets, 25 mg, 50 mg Revolade® GlaxoSmithKline Australia Pty Ltd	Decreased platelet count	Amend continuation restriction to allow continuation of treatment with eltrombopag in patients whose disease is stable and responding to treatment with romiplostim or vice versa.
New listing (Minor submission)	ENOXAPARIN SODIUM 20 mg/0.2 mL injection, 10 x 0.2 mL pre-filled syringes 40 mg/0.4 mL injection, 10 x 0.4 mL pre-filled syringes 60 mg/0.6 mL injection, 10 x 0.6 mL pre-filled syringes 80 mg/0.8 mL injection, 10 x 0.8 mL pre-filled syringes 100 mg/1 mL injection, 10 x 1 mL pre-filled syringes Clexane Safety-Lock® Sanofi-Aventis Australia Pty Ltd.	Prevention of blood clots	To request listing of a new presentation of safety-lock pre-filled syringes on the PBS
PBS review (Major Submission)	EZETIMIBE + SIMVASTATIN ezetimibe 10 mg + simvastatin 10 mg tablet, 30 ezetimibe 10 mg + simvastatin 20 mg tablet, 30 ezetimibe 10 mg + simvastatin 40 mg tablet, 30 ezetimibe 10 mg + simvastatin 80 mg tablet, 30 Vytorin® Merck Sharp and Dohme (Australia) Pty Ltd	Hypercholesterolaemia	To present evidence to quantify the compliance benefit provided by the fixed dose combination (FDC) product with the purpose of maintaining the current advice under Section 101 (4AC) of the *National Health Act 1953*.

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New listing (Major submission)	EZETIMIBE+ATORVASTATIN ezetimibe 10 mg + atorvastatin 10 mg tablet, 30 ezetimibe 10 mg + atorvastatin 20 mg tablet, 30 ezetimibe 10 mg + atorvastatin 40 mg tablet, 30 ezetimibe 10 mg + atorvastatin 80 mg tablet, 30 Atozet® Merck Sharp and Dohme (Australia) Pty Ltd	Hypercholesterolaemia	Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia in patients who meet certain criteria.
New listing (Minor submission)	GLUCOSE INDICATOR BLOOD glucose indicator blood strip: diagnostic, 50, Dario® Blood Glucose Test Strip uHealth Australia Pty Ltd	Diabetes	Unrestricted benefit listing.
Change to listing (Minor submission)	IRON SUCROSE iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules, Venofer® Aspen Pharmacare Australia Pty Ltd	Iron deficiency anaemia	To request removal of the requirements to be used in combination with an erythropoiesis stimulating agent and hypersensitivity reaction to iron polymaltose from the current restriction, to align it with the current restriction for iron polymaltose.
New listing (Minor submission)	ITRACONAZOLE 50 mg capsule, 60 Lozanoc® Mayne Pharma International Ltd	Systemic fungal infections	Authority Required (STREAMLINED) listing of a 50 mg capsule for the same indications as the currently PBS listed 100 mg capsule.

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Change to recommended listing (Minor submission)	IVACAFTOR, tablet, 150 mg, Kalydeco® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic Fibrosis	To request an extension of the PBAC's previous recommendation for the PBS listing of ivacaftor as a Section 100 (Highly Specialised Drugs Program) benefit for the treatment of cystic fibrosis (CF) in patients aged six years and older who have a G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene to include other gating (class III) mutation in the CFTR gene.
Change to listing (Major submission)	LEUPRORELIN 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack Lucrin Depot PDS® AbbVie Pty Ltd	Central Precocious Puberty	Extend the current Authority Required (STREAMLINED) listing to include the treatment of central precocious puberty.
New listing (Minor submission)	MERCAPTOPURINE 20 mg/mL oral suspension, 100 mL, Allmercap® Link Healthcare Pty Ltd	Acute lymphoblastic leukaemia	Authority Required listing for the treatment of acute lymphoblastic leukaemia in paediatric patients when the tablet form is unsuitable.
New listing (Minor submission)	MESALAZINE 4 g granules: modified release, 30 x 4 sachets, Pentasa® Ferring Pharmaceuticals Pty Ltd	Inflammatory bowel disease (Crohn disease and Ulcerative colitis)	Authority Required (STREAMLINED) listing of a new strength for the treatment of Crohn disease and ulcerative colitis.

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New listing (Minor submission)	MESALAZINE 3 g granules: modified release, 30 sachets, Salofalk® Aspen Australia Pty Ltd	Ulcerative colitis	Authority Required (STREAMLINED) listing of a new strength for the treatment of ulcerative colitis where hypersensitivity to sulfonamides exists or where intolerance to sulfasalazine exists.
New Listing (Major submission)	NITISINONE 2 mg capsule, 60 5 mg capsule, 60 10 mg capsule, 60 Orfadin® A.Menarini Australia Pty Ltd	Hereditary tyrosinaemia type 1	Section 100 Authority Required listing for the treatment of hereditary tyrosinaemia type 1.
New Listing (Major submission)	OCRIPLASMIN 0.5 mg/0.2 mL injection, 1 x vial Jetrea® Alcon Laboratories (Australia) Pty Ltd	Vitreomacular traction	Authority Required listing for the treatment of vitreomacular traction in patients who meet certain criteria.
New Listing (Major submission)	OFATUMUMAB 100 mg/5 mL injection, 5 mL vial 1 g/50 mL injection, 50 mL vial Arzerra® GlaxoSmithKline Australia Pty Ltd	Chronic Lymphocytic Leukaemia	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with chronic lymphocytic leukaemia who meet certain criteria.

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Change to listing (Minor submission)	OMALIZUMAB 75 mg/0.5 mL injection, 1 x 0.5 mL syringe 150 mg/mL injection, 1 x 1 mL syringe 150 mg injection [1 x 150 mg vial] (&) inert substance diluent [1 x 1.2 mL ampoule], 1 pack, Xolair® Novartis Pharmaceuticals Australia Pty Ltd	Severe allergic asthma	To propose revision of PBS restrictions and implementation requirements for omalizumab for the treatment of severe allergic asthma.
Change to listing (Minor submission)	OXYCODONE 10 mg modified release tablets 15 mg modified release tablets 20 mg modified release tablets 30 mg modified release tablets 40 mg modified release tablets 80 mg modified release tablets OxyContin® MR Mundipharma Pty Ltd	Chronic severe disabling pain	To amend the existing listing such that generic oxycodone tablets without a claimed abuse-resistant formulation cannot be substitutable with OxyContin by a dispensing pharmacist (i.e. not 'a' flagged). The submission further requests the PBAC consider quality use of medicines issues related to the listing of generic oxycodone tablets that do not have abuse-resistant formulation properties.
New listing (Minor submission)	PARACETAMOL 665 mg tablet: modified release, 96 tablets Paracetamol Osteo Tab AFT Pharmaceuticals Pty Ltd	Pain	Restricted Benefit listing for the relief of persistent pain associated with osteoarthritis and an Authority Required listing for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated.

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New Listing (Major submission)	PEGINTERFERON BETA-1A 63 microgram/0.5 mL injection, 0.5 mL syringe + 94 microgram/0.5 mL injection, 0.5 mL syringe 63 microgram/0.5 mL injection, 0.5 mL injection device + 94 microgram/0.5 mL injection, 0.5 mL injection device 125 microgram/0.5 mL injection, 2 x 0.5 mL syringes 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices Plegridy® Biogen Idec Australia Pty Ltd	Multiple sclerosis	Authority Required (STREAMLINED) listing for the treatment of multiple sclerosis in patients who meet certain criteria.
New listing (Major submission)	PERTUZUMAB 420 mg/14 mL injection, 1 x 14 mL vial Perjeta® Roche Products Pty Ltd	Breast cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with HER2 positive metastatic breast cancer who meet certain criteria.
New listing (Minor submission) WITHDRAWN	PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES 25 microgram/0.5 mL, 1 x 0.5 mL pre-filled syringe, Pneumovax® 23 bioCSL (Australia) Pty Ltd	Pneumococcal infection	To request the listing of a new presentation of a pre-filled syringe on the PBS and NIP.
New listing (Minor submission)	POMALIDOMIDE, capsules, 3 mg and 4 mg, Pomalyst® Celgene Pty Ltd	Myeloma	To propose a re-specified base case and revised inputs to the economic model following the July 2014 PBAC consideration for the treatment in combination with dexamethasone, of patients with relapsed and/or refractory multiple myeloma who have received and failed prior treatment with both lenalinomide and bortezomib.

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New Listing (Major submission)	PONATINIB 15 mg tablet, 60 45 mg tablet, 30 Iclusig® Specialised Therapeutics Australia Pty Ltd	Chronic myeloid leukaemia	Authority Required listing for the treatment of chronic myeloid leukaemia (CML) in patients who meet certain criteria.
Change to listing (Minor submission)	RANIBIZUMAB 2.3 mg/0.23 mL, 1 x 0.23 mL vial 1.65 mg/0.165 mL, pre-filled syringe, Lucentis® Novartis Pharmaceuticals Australia Pty Ltd	Neovascular age-related macular degeneration	To request ranibizumab pre-filled syringe and vial presentations be “a” flagged.
New Listing (Major submission)	RIOCIGUAT 500 microgram tablet, 42 and 84 1 mg tablet, 42 and 84 1.5 mg tablet, 42 and 84 2 mg tablet, 42 and 84 Adempas® Bayer Australia Ltd	Chronic thromboembolic pulmonary hypertension	Section 100 Authority Required listing for the treatment of chronic thromboembolic pulmonary hypertension.
New listing (Minor submission)	RITUXIMAB 1,400 mg/11.7 mL injection, Mabthera® SC Roche Products Pty Ltd	Non-Hodgkin’s lymphoma	Authority Required listing of a new subcutaneously administered formulation of rituximab for patients with non-Hodgkin’s lymphoma.

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Change to listing (Minor submission)	SALBUTAMOL salbutamol 200 microgram inhalation: powder for, 100 capsules, Ventolin Rotacap® GlaxoSmithKline Pty Ltd	Asthma	Amend maximum quantity and number of repeats to align with a new pack size.
Change to listing (Minor submission)	SECTION 100 HIGHLY SPECIALISED DRUGS PROGRAM ITEMS, all drugs, The Pharmacy Guild of Australia, Australasian Society for HIV medicine, Arthritis Australia, Consumers Health Forum, Cystic Fibrosis Australia, COTA Australia, Federation of Ethnic Communities' Councils of Australia, Hepatitis Australia, Pharmaceutical Society of Australia	Various	Amend the current Authority Required supply arrangements for all items listed as Section 100 (Highly Specialised Drugs Program) benefits by having single PBS item codes, with the effect of removing the current public hospital and private hospital dispensing differentiation to enable uniform prescribing and supply arrangements, in line with previous recommendations made for HIV antiretroviral therapies and clozapine under the Highly Specialised Drugs Program.
Change to listing (Minor submission)	SORAFENIB 200 mg tablet Nevaxar® Bayer Australia Ltd	Renal cell carcinoma (RCC)	Extend the current Authority Required listing to include the treatment of stage IV clear cell variant renal cell carcinoma (advanced RCC) in patients who have failed first line treatment.
New Listing (Major submission)	SUCROFERRIC OXYHYDROXIDE Iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90 Velphoro® Vifor Pharma Pty Ltd	Hyperphosphataemia	General schedule listing (maintenance therapy) and Section 100 Authority Required (initiation of therapy) listings for the management of hyperphosphataemia in patients with chronic kidney disease who meet certain criteria.

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New listing (Major submission) WITHDRAWN	TAFLUPROST+TIMOLOL tafluprost 0.0015% + timolol 0.5%, 30 x 0.3 mL unit doses Taptiqom® Merck Sharp and Dohme (Australia) Pty Ltd	Elevated intra-ocular pressure	Restricted Benefit listing of a fixed dose combination product for the treatment of elevated intra-ocular pressure.
New listing (Major submission)	TALIGLUCERASE ALFA 200 units injection, 1 vial Elelyso® Pfizer Australia Pty Ltd	Type 1 Gaucher Disease	Section 100 Authority Required listing for the treatment of type 1 Gaucher disease in patients who meet certain criteria.
New listing (Major submission)	TRAMETINIB 500 microgram tablet, 30 1 mg tablet, 30 2 mg tablet, 30 Mekinist® GlaxoSmithKline Australia Pty Ltd	Melanoma	To provide further information to support a request for a managed entry scheme to allow the listing of trametinib as an Authority Required listing for the treatment of patients with melanoma who meet certain criteria.
New listing (Major submission)	TRASTUZUMAB EMTANSINE 100 mg injection, 1 x 100 mg vial 160 mg injection, 1 x 160 mg vial Kadcyla® Roche Products Pty Ltd	Breast Cancer	Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) benefit for the treatment of patients with HER2 positive metastatic breast cancer who meet certain criteria.

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Change to recommended listing (Minor submission)	UMECLIDINIUM BROMIDE + VILANTEROL TRIFENATATE (FDC) umeclidinium bromide 62.5 microgram/actuation + vilanterol trifenatate 25 microgram/actuation inhalation: powder for Anoro® Ellipta® GlaxoSmithKline Australia Pty Ltd	Chronic obstructive pulmonary disease	Amend recommended restriction to also include patients who have symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist and/or long acting beta2 agonist in addition to those already stabilised on a combination of a long acting muscarinic antagonist and long acting beta2 agonist.
Change to listing (Major submission)	USTEKINUMAB 45 mg/0.5 mL injection, 1 x 0.5mL vial Stelara® Janssen-Cilag Pty Ltd	Psoriatic arthritis	Authority Required listing for the treatment of patients with severe active psoriatic arthritis who meet certain criteria.
New listing (Major submission)	ZOSTER VIRUS VACCINE LIVE 0.65 mL injection, prefilled syringe Zostavax® bioCSL (Australia) Pty Ltd	Immunisation against herpes zoster (shingles)	National Immunisation Program (NIP) listing for persons 70 years of age.