

NOVEMBER 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ADALIMUMAB</p> <p>Injection 80 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe</p> <p>Humira®</p> <p>AbbVie Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Moderate to severe hidradenitis suppurativa (HS)</p>	<p>To request an Authority Required listing of a new form of adalimumab for the treatment of patients with HS under the same conditions as current listings.</p>	<p>The PBAC recommended an Authority Required listing of adalimumab 80 mg/0.8 mL pre-filled pens and syringes for the treatment of moderate to severe HS at the same cost per milligram as the 40 mg/0.8mL form. The PBAC considered the listing was likely to be cost neutral to Government.</p>
<p>AMINO ACID FORMULA WITH CARBOHYDRATE, WITHOUT PHENYLALANINE</p> <p>Tablet 1.25 g, 462</p> <p>PKU Easy Tablet®</p> <p>Orpharma Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Phenylketonuria (PKU)</p>	<p>To request a Restricted Benefit listing for the dietary management of patients with PKU.</p>	<p>The PBAC recommended the Restricted Benefit listing of amino acid formula with carbohydrate without phenylalanine (PKU Easy Tablet®) for the dietary management of PKU on a cost-minimisation basis to Phlexy-10® at an equivalent cost per gram of protein equivalent.</p>

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<p>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, WITHOUT METHIONINE</p> <p>Tablets 0.91 g, 462</p> <p>HCU Easy Tablet®</p> <p>Orpharma Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Pyridoxine non-responsive homocystinuria (HCU)</p>	<p>To request a Restricted Benefit listing for the dietary management of patients with pyridoxine non-responsive HCU.</p>	<p>The PBAC recommended the Restricted Benefit listing of amino acid formula with fat, carbohydrate without methionine (HCU Easy Tablet®) for the dietary management of pyridoxine non-responsive HCU on a cost-minimisation basis to HCU Cooler 20® at an equivalent cost per gram of protein equivalent.</p>
<p>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, WITHOUT PHENYLALANINE AND TYROSINE</p> <p>Tablets 0.91 g, 462</p> <p>TYR Easy Tablet®</p> <p>Orpharma Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Tyrosinaemia (TYR)</p>	<p>To request a Restricted Benefit listing for the dietary management of patients with TYR.</p>	<p>The PBAC recommended the Restricted Benefit listing of amino acid formula with fat, carbohydrate without phenylalanine and tyrosine (TYR Easy Tablet®) for the dietary management of TYR on a cost-minimisation basis to TYR Cooler 15® at an equivalent cost per gram of protein equivalent. The proposed listing was supported by the Nutritional Products Working Party.</p>

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<p>AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, WITHOUT VALINE, LEUCINE AND ISOLEUCINE</p> <p>Tablets 1.25 g, 462</p> <p>MSUD Easy Tablet®</p> <p>Orpharma Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Maple syrup urine disease (MSUD)</p>	<p>To request a Restricted Benefit listing for the dietary management of patients with MSUD.</p>	<p>The PBAC recommended the Restricted Benefit listing of amino acid formula (MSUD Easy Tablet®) for the dietary management of MSUD on a cost-minimisation basis to MSUD Express 20® at an equivalent cost per gram of protein equivalent.</p>
<p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE</p> <p>Sachets containing oral powder 12.5 g, 30</p> <p>MSUD Explore 5®</p> <p>Vitaflo Australia Pty Limited</p> <p>New Listing (Minor Submission)</p>	<p>Maple syrup urine disease (MSUD)</p>	<p>To request a Restricted Benefit listing for the dietary management of patients with MSUD.</p>	<p>The PBAC recommended the Restricted Benefit listing of amino acid formula (MSUD Explore 5®) for the dietary management of MSUD, on a cost-minimisation basis with MSUD Gel® at an equivalent cost per gram of protein equivalent.</p>

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<p>ATEZOLIZUMAB</p> <p>Solution concentrate for I.V. infusion 840 mg in 14 mL</p> <p>Tecentriq®</p> <p>Roche Products Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request the addition of a new vial size and to amend the current dosing regimens of atezolizumab for second-line (2L) and first-line (1L) NSCLC to allow clinician choice of either:</p> <ul style="list-style-type: none"> • 1,200 mg Q3W dosing, or • 1,680 mg Q4W dosing. 	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new form of atezolizumab (840 mg in 14 mL) and addition of a new dosing regimen 1680 mg every four weeks (Q4W) to the existing dosing regimen, 1200 mg every three weeks (Q3W), for the PBS indications for 2L treatment of locally advanced or metastatic NSCLC and 1L treatment of stage IV metastatic non-squamous NSCLC. The PBAC recommended 1680 mg Q4W dosing of atezolizumab when administered as monotherapy in 2L NSCLC, and for continuing treatment after cessation of platinum doublet-chemotherapy and bevacizumab in 1L NSCLC.</p> <p>The PBAC considered that atezolizumab 840 mg injection would need to be included within the existing subsidisation caps of the Risk Sharing Arrangement in place for the currently listed indications.</p>

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<p>ATEZOLIZUMAB</p> <p>Solution concentrate for I.V. infusion 1200 mg in 20 mL</p> <p>Tecentriq®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Small cell lung cancer (SCLC)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of patients with extensive stage (ES) SCLC.</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of atezolizumab, for use in combination with a platinum-based chemotherapy and etoposide, for previously untreated patients with ES SCLC and an Eastern Cooperative Oncology Group score of 0-1.</p> <p>The PBAC considered there is a high clinical need for effective treatments for ES-SCLC. The PBAC was satisfied that atezolizumab + a platinum-based chemotherapy + etoposide provides, for some patients, a significant improvement in efficacy over platinum-based chemotherapy + etoposide alone. However, the PBAC considered that the magnitude and durability of the benefit was uncertain, especially given the short duration of follow-up in the trial.</p> <p>The PBAC noted that the resubmission had amended the economic model and proposed a lower price and reduced total financial expenditure compared with the previous submission. The PBAC considered these changes adequately addressed the Committee's previous concerns. The PBAC was satisfied that the incremental cost-effectiveness ratio was acceptable at the price applied in the economic model, and with the proposed Risk Sharing Arrangement.</p>

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<p>BOTULINUM TOXIN TYPE A</p> <p>Lyophilised powder for injection 100 units</p> <p>Botox®</p> <p>Allergan Australia Pty Limited</p> <p>Change to listing (Minor Submission)</p>	<p>Spasticity of the upper limb</p>	<p>To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for moderate to severe spasticity of the upper limb following a stroke to include the treatment of patients with moderate to severe spasticity of the upper limb following an acute event, consistent with the March 2019 PBAC recommendation for clostridium botulinum type A (Dysport®).</p>	<p>The PBAC recommended the extension of the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for botulinum toxin type A (Botox®) for the treatment of moderate to severe focal spasticity of the upper limb following a stroke, to also include spasticity following acute events other than stroke.</p> <p>Although it was not feasible to conduct an indirect comparison between Botox® and Dysport® due to small patient numbers and varying patient and trial characteristics in the available trials, the PBAC was satisfied that Botox® was non-inferior to Dysport® in terms of comparative-effectiveness and safety, given the established interchangeability between them in post-stroke upper limb spasticity.</p> <p>Based on the maximum dispensed quantity of Botox® for upper limb spasticity, the PBAC considered that the equi-effective doses of Botox® and Dysport® were: Botox® 1U = Dysport® 3.75U. The PBAC considered that the extension of the listing for Botox® should be cost neutral to the PBS and recommended that Botox® should be included in the Risk Sharing Arrangement in place for Dysport®.</p>

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<p>BRIGATINIB</p> <p>Tablet 30 mg Tablet 90 mg Tablet 180 mg Pack containing 7 tablets containing brigatinib 90 mg and 21 tablets containing brigatinib 180 mg</p> <p>Alunbrig®</p> <p>Takeda Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request an Authority Required listing for the treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC.</p>	<p>The PBAC recommended the Authority Required listing of brigatinib as monotherapy for the treatment of patients with locally advanced (Stage IIIB) or metastatic (Stage IV) ALK-positive non-squamous or not otherwise specified NSCLC. The PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of brigatinib would be acceptable if it were cost-minimised against alectinib. In making this recommendation, the PBAC considered that the listing of brigatinib would provide an alternative ALK-tyrosine kinase inhibitor with intracranial activity and a different profile in terms of safety and tolerability.</p>

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<p>BRIVARACETAM</p> <p>Tablet 25 mg Tablet 50 mg Tablet 75 mg Tablet 100 mg Oral solution 10 mg per mL, 300 mL</p> <p>Briviact®</p> <p>UCB Australia Proprietary Limited</p> <p>Change to listing (Major Submission)</p>	<p>Epilepsy</p>	<p>To request a change to the current Authority Required (STREAMLINED) listings for the treatment of patients with intractable partial epileptic seizures, to allow use in patients aged less than 16 years.</p>	<p>The PBAC recommended changing the Authority Required (STREAMLINED) listings for brivaracetam for the treatment of intractable partial onset epileptic seizures, to include patients aged 4 to 15 years. Its recommendation was based on, among other matters, its assessment that the cost-effectiveness of brivaracetam would remain acceptable with the extended listing implemented at the current price, where the listing results in an overall saving to Government. In making its recommendation, the PBAC acknowledged the clinical need for drugs that are effective in reducing seizure frequency in patients who have failed other lines of anti-epileptic drug treatment.</p> <p>The PBAC noted that the TGA registered indications for both brivaracetam and lacosamide are as add-on therapy in the treatment of partial seizures in patients with epilepsy who are aged 4 years and older. The PBAC recommended removing the age criterion from the brivaracetam restriction, in line with the restriction for lacosamide.</p> <p>The PBAC further recommended that the continuation criteria ‘treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent’ be removed from listings for this drug. It noted this change would enable patients to use brivaracetam as eventual dual or monotherapy, and considered this would also allow ineffective medications to be ceased, reducing treatment burden and treatment-related toxicity.</p>

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<p>BUDESONIDE + FORMOTEROL</p> <p>Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses</p> <p>Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses</p> <p>Symbicort® Turbuhaler® 200/6; Symbicort® Rapihaler® 100/3</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Asthma</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the first-line treatment of patients with mild asthma.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of budesonide with formoterol fixed dose combination (Symbicort®) for use as an anti-inflammatory reliever therapy administered as needed for adolescent and adult patients with mild asthma. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Symbicort® would be acceptable if it were cost-minimised to inhaled corticosteroid maintenance regimen plus short-acting beta2-agonist as needed.</p>

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<p>BUPRENORPHINE</p> <p>Injection (modified release) 100 mg in 0.5 mL pre-filled syringe</p> <p>Injection (modified release) 300 mg in 1.5 mL pre-filled syringe</p> <p>Sublocade®</p> <p>Indivior Pty Ltd</p> <p>New listing (Matters Outstanding)</p>	<p>Opiate use disorder (OUD)</p>	<p>Consider the deferred request for a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients OUD.</p>	<p>The PBAC recommended the Section 100 (Opiate Dependence Treatment Program) Restricted Benefit listing of buprenorphine modified release injection (Sublocade®) for the treatment of OUD. The PBAC’s recommendation was based on, among other matters, its assessment that the cost-effectiveness of Sublocade® would be acceptable if it were cost-minimised to Buvidal® on a cost per patient per day basis.</p>
<p>CERTOLIZUMAB PEGOL</p> <p>Solution for injection 200 mg in 1 mL pre-filled pen</p> <p>Solution for injection 200 mg in 1 mL single use pre-filled syringe</p> <p>Cimzia®</p> <p>UCB Australia Proprietary Limited</p> <p>Change to listing (Major Submission)</p>	<p>Non-radiographic axial spondyloarthritis (nr-axSpA)</p>	<p>To request an Authority Required listing for the treatment of patients with nr-axSpA who meet certain conditions.</p>	<p>The PBAC recommended the Authority Required listing of certolizumab pegol for the treatment of nr-axSpA. The PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of certolizumab pegol would be acceptable if it were cost-minimised to golimumab. The PBAC advised the equi-effective doses were certolizumab pegol 400 mg at Week 0, 2, 4 followed by 200 mg every 2 weeks or 400 mg every 4 weeks and golimumab 50 mg once a month.</p>

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<p>DARUNAVIR + COBICISTAT+ EMTRICITABINE + TENOFOVIR ALAFENAMIDE</p> <p>Tablet containing darunavir 800 mg with cobicistat 150 mg with emtricitabine 200 mg and tenofovir alafenamide 10 mg</p> <p>Symtuza®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Human immunodeficiency virus (HIV) infection</p>	<p>To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection.</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program – Community Access), Authority Required (STREAMLINED) listing of the combination drug darunavir with cobicistat with emtricitabine and tenofovir alafenamide (Symtuza®) for the treatment of HIV infection, on a weighted cost minimisation basis with alternative treatments.</p> <p>The PBAC considered the alternative treatments for the cost-minimisation to be Prezcobix® (darunavir/cobicistat) and Truvada® (tenofovir disoproxil/emtricitabine) for most patients, and Prezcobix® and Descovy® (tenofovir alafenamide/emtricitabine) for patients with renal impairment who cannot use Truvada®. The PBAC considered the safety and effectiveness of Symtuza® to be similar to the known profiles of its component drugs, taken concomitantly.</p>
<p>DIMETHYL FUMARATE</p> <p>Capsule (modified release) 120 mg Capsule (modified release) 240 mg</p> <p>Tecfidera®</p> <p>Biogen Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Relapsing-remitting multiple sclerosis (RRMS)</p>	<p>To request the current Authority Required listings of dimethyl fumarate for the treatment of patients with RRMS be changed to Authority Required (STREAMLINED).</p>	<p>The PBAC recommended amending the existing listings of dimethyl fumarate to Authority Required (STREAMLINED) for the treatment of RRMS.</p> <p>The PBAC also recommended changing the authority level of the current listings for fingolimod, teriflunomide and cladribine for the treatment of RRMS to Authority Required (STREAMLINED).</p>

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<p>DURVALUMAB</p> <p>Solution concentrate for I.V. infusion 120 mg in 2.4 mL Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p>Imfinzi®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy.</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of durvalumab for the treatment of Stage III unresectable NSCLC in patients who have not progressed after platinum-based chemoradiation therapy. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of durvalumab would be acceptable with a small reduction to the price proposed in the resubmission.</p>
<p>EVOLOCUMAB</p> <p>Injection 420 mg in 3.5 mL single use pre-filled cartridge Injection 140 mg in 1 mL single use pre-filled pen</p> <p>Repatha®</p> <p>Amgen Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Hypercholesterolaemia</p>	<p>Resubmission to request an Authority Required listing for the treatment of patients with hypercholesterolaemia who are very high risk for atherosclerotic cardiovascular disease (ASCVD) and who are inadequately controlled on optimal doses of high potency statins and ezetimibe.</p>	<p>The PBAC recommended the Authority Required listing of evolocumab for the treatment of non-familial hypercholesterolaemia in patients who have ASCVD and additional high-risk factors. The PBAC also recommended an extension to the current listings of evolocumab for the treatment of familial hypercholesterolaemia to include patients with ASCVD who have an LDL level between 2.6 and 3.3 mmol/L.</p> <p>The PBAC considered that there is a moderate unmet clinical need in this patient population, and that there are important clinical benefits associated with evolocumab therapy including a reduction in non-fatal heart attacks and strokes, which would result in a likely reduction in the risk of death.</p> <p>The PBAC considered that the cost-effectiveness of evolocumab would be acceptable at the price proposed in the minor resubmission, and if use is confined to this high-risk population.</p>

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<p>GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS</p> <p>Sachets containing oral powder 16 g, 60 Sachets containing oral powder 32 g, 30</p> <p>PKU Build 10® PKU Build 20®</p> <p>Cortex Health Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Phenylketonuria</p>	<p>To request changes to the formulation of PKU Build 10® and PKU Build 20®.</p>	<p>The PBAC recommended continuing the listing of the glycomacropeptide formula, PKU Build®, on the PBS following its reformulation. The PBAC noted the low levels of dietary folate, choline and methionine and recommended adding an administrative note to that effect to the listing.</p>
<p>HIGH DOSE INACTIVATED TRIVALENT INFLUENZA VACCINE (SPLIT VIRION)</p> <p>Injection 0.5 mL</p> <p>Fluzone® High-Dose</p> <p>Sanofi-Aventis Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Prevention of seasonal influenza</p>	<p>Resubmission to request that the PBAC review the circumstances of the recommended National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.</p>	<p>The PBAC recommended an increase in the price of inactivated trivalent influenza vaccine (Fluzone® High-Dose, TIV-HD), on the NIP for active immunisation against influenza in adults aged ≥ 65 years. The PBAC recommendation was on the basis that, on balance, TIV-HD was at least as effective as adjuvanted quadrivalent influenza vaccine (Fluad® Quad, aQIV). The PBAC considered a claim of superior effectiveness compared with aQIV could not be adequately supported by the clinical evidence presented and therefore a cost-minimisation approach in which TIV-HD was the same price as aQIV would be appropriate.</p>

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<p>IBRUTINIB</p> <p>Capsule 140 mg</p> <p>Imbruvica®</p> <p>Janssen-Cilag Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p>	<p>Resubmission to request an Authority Required listing for the treatment of patients with previously untreated CLL or SLL with evidence of one or more 17p chromosome deletions.</p>	<p>The PBAC recommended the Authority Required listing of ibrutinib for first-line treatment of CLL/SLL patients with deletion 17p. The PBAC recognised the high clinical need for effective treatments in this population and was satisfied that ibrutinib provides, for some patients, a significant improvement in progression-free survival over obinutuzumab + chlorambucil. In addition, the PBAC considered that it was reasonable to assume non-inferior safety of ibrutinib monotherapy compared with obinutuzumab + chlorambucil during the first 9 months of treatment and inferior safety thereafter. The PBAC considered ibrutinib was cost-effective in the proposed population if the price of ibrutinib was the same as for the relapsed/refractory CLL/SLL PBS listing.</p>
<p>INACTIVATED QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION)</p> <p>Injection 0.5 mL</p> <p>FluQuadri™</p> <p>Sanofi-aventis Healthcare Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Prevention of seasonal influenza</p>	<p>To request an extension to the current National Immunisation Program (NIP) listing of FluQuadri™ to include all people aged 6 months and older currently eligible for seasonal influenza vaccination under the NIP for the prevention of seasonal influenza.</p>	<p>The PBAC recommended extending the current listing of quadrivalent influenza vaccine (QIV) (split virion, inactivated), FluQuadri™, on the NIP for the prevention of influenza, to at-risk children (i.e. children with certain medical conditions putting them at increased risk of severe influenza and complications, and all Aboriginal and Torres Strait Islander children) aged 6-35 months, and all healthy children aged 6 months to <5 years.</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment, that:</p> <ul style="list-style-type: none"> • the cost-effectiveness of FluQuadri™ would be acceptable if it were cost-minimised against an alternative QIV such as FluQuadri Junior™, Fluarix Tetra™ or Vaxigrip Tetra™, on the basis that FluQuadri™ is non-inferior to currently listed and recommended QIVs for at-risk children aged 6-35 months; and • the cost-effectiveness of FluQuadri™ would be acceptable if it were cost-minimised against Vaxigrip Tetra™, on the basis that FluQuadri™ is non-inferior to Vaxigrip Tetra™ for healthy children aged 6 months to <5 years.

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<p>INCOBOTULINUMTOXIN A</p> <p>Lyophilised powder for injection 100 units</p> <p>Xeomin®</p> <p>Merz Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Spasticity of the upper limb</p>	<p>To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for moderate to severe spasticity of the upper limb following a stroke to include the treatment of patients with moderate to severe spasticity of the upper limb following an acute event, consistent with the March 2019 PBAC recommendation for clostridium botulinum type A (Dysport®).</p>	<p>The PBAC recommended the extension of the current Section 100 (Botulinum Toxin Program), Authority Required (STREAMLINED) listing for incobotulinumtoxin A (Xeomin®) for the treatment of moderate to severe focal spasticity of the upper limb following a stroke, to also include spasticity following acute events other than stroke.</p> <p>The PBAC was satisfied that Xeomin® was non-inferior to Dysport® in terms of comparative effectiveness and safety given the established interchangeability between both drugs in post-stroke upper limb spasticity.</p> <p>Based on the maximum dispensed quantity of Xeomin® for upper limb spasticity, the PBAC considered that the equi-effective doses of Xeomin® and Dysport® were: Xeomin® 1U = Dysport® 3.75U. The PBAC considered that the extension of the listing for Xeomin should be cost neutral to the PBS and recommended that Xeomin® be included in the current Risk Sharing Arrangement in place for Dysport®.</p>
<p>ISOTRETINOIN</p> <p>Capsule 30 mg</p> <p>Oratane®</p> <p>Oraderm Pharmaceuticals Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Severe cystic acne</p>	<p>To request an Authority Required (STREAMLINED) listing of a new form of isotretinoin for the treatment of patients with severe cystic acne.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of isotretinoin, in the form of 30 mg capsule, for the treatment of patients with severe cystic acne. The PBAC considered it would be appropriate to list the 30 mg strength at a price per milligram equivalent to the lowest price per milligram isotretinoin capsule currently listed on the PBS.</p>

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<p>LEVODOPA + CARBIDOPA</p> <p>Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL</p> <p>Duodopa®</p> <p>AbbVie Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Parkinson disease</p>	<p>To request:</p> <ul style="list-style-type: none"> • General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings with a new maximum quantity of 4 packs, with the same listing conditions as the current listings. • An additional clinical criterion for the current listings: 'patient must require continuous administration without an overnight break or a total dose per day of levodopa > 2000 mg' 	<p>The PBAC recommended additional General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings for levodopa with carbidopa monohydrate intestinal gel (Duodopa®) for the treatment of advanced Parkinson's disease, with a reduced maximum quantity of 4 packs.</p> <p>The PBAC recommended the addition of a clinical criterion to the current listings for Duodopa® with a maximum quantity of 8 packs to restrict access to patients requiring more than 1 cassette per day.</p> <p>The PBAC considered the proposed changes would reduce the risk of some patients using Duodopa® beyond its limited shelf-life.</p>
<p>LORLATINIB</p> <p>Tablet 25 mg Tablet 100 mg</p> <p>Lorviqua®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request an Authority Required listing for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive NSCLC who previously treated with one or more ALK-tyrosine kinase inhibitors (TKI).</p>	<p>The PBAC recommended the Authority Required listing of lorlatinib as monotherapy for the treatment of patients with metastatic (Stage IV) ALK-positive NSCLC who have disease progression either following treatment with crizotinib and at least one other ALK-TKI, or an ALK-TKI other than crizotinib in the second-line and subsequent-line settings. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of lorlatinib would be acceptable if it were cost-minimised to alectinib. In making this recommendation, the PBAC considered that there is a high unmet clinical need for effective treatments with broader mutational coverage and intracranial activity for this patient population.</p>

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<p>MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE</p> <p>Injection 0.5 mL</p> <p>Bexsero®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Prevention of meningococcal B disease</p>	<p>Resubmission to request listing on the National Immunisation Program (NIP) for the routine immunisation of infants and adolescents, and catch-up programs for high risk populations for the prevention of invasive meningococcal disease (IMD) caused by Neisseria (N.) meningitidis group B strains.</p>	<p>The PBAC recommended the listing of multicomponent meningococcal group B vaccine (4CMenB, Bexsero®), on the NIP, for the prevention of IMD caused by N. meningitidis group B strain in Aboriginal and Torres Strait Islander children.</p> <p>The PBAC noted the cost-effectiveness of the vaccine was highly dependent on the incidence of IMD caused by the group B strain and the incidence was more than 6 times higher in Aboriginal and Torres Strait Islander children under 5 years of age compared with non-Indigenous children. The PBAC considered 4CMenB was likely to be cost-effective for the routine vaccination of Aboriginal and Torres Strait Islander infants at the price proposed in the resubmission given the high and disproportionate burden of disease in this population. The PBAC recommended implementation of a catch-up program for Aboriginal and Torres Strait Islander children up to 2 years of age.</p> <p>The PBAC also considered 4CMenB was likely to be cost-effective in children and adults with medical conditions associated with increased risk of IMD (specifically, people with asplenia and hyposplenia, complement deficiency and those undergoing treatment with eculizumab) and recommended listing on the NIP for routine vaccination of this population.</p> <p>The PBAC did not recommended listing for a broader population of infants or for adolescents due to the remaining uncertainties regarding the magnitude of clinical effectiveness of 4CMenB, and the lack of any herd protective effects, which inform the cost effectiveness.</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p>Opdivo®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Change to listing (Matters Outstanding)</p>	<p>Melanoma</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III or Stage IV malignant melanoma.</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing of nivolumab for the adjuvant treatment of completely resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma.</p> <p>The PBAC noted changes made to the economic analysis and considered that the uncertainty surrounding uptake in the adjuvant setting and changes to use in the unresectable or metastatic setting would be managed by subsidisation caps through a Risk Sharing Arrangement.</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>NIVOLUMAB AND IPILIMUMAB</p> <p>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</p> <p>Opdivo® Yervoy®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Melanoma</p>	<p>Resubmission to request an extension of the existing Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for nivolumab and ipilimumab for the treatment of unresectable Stage III or IV malignant melanoma to allow use as first-line therapies in patients who are BRAF V600 mutation positive.</p>	<p>The PBAC recommended the extension of the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for nivolumab (NIVO) monotherapy and nivolumab in combination with ipilimumab (NIVO+IPI) to allow their use as first-line therapies in the treatment of BRAF V600 mutant positive Stage III or Stage IV unresectable or metastatic melanoma. The PBAC considered the claim of non-inferior efficacy between NIVO monotherapy, NIVO+IPI combination therapy and DAB+TRAM was likely to be supported by the data, and advised that there should be no additional cost to the PBS as a result of the restriction changes.</p>
<p>PEGFILGRASTIM</p> <p>Injection 6 mg in 0.6 mL single use pre-filled syringe</p> <p>Ziextenzo®</p> <p>Sandoz Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Chemotherapy-induced neutropenia</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a biosimilar pegfilgrastim under the same conditions as the reference biologic.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of the biosimilar brand of pegfilgrastim, (Ziextenzo®), on the Section 100 (Highly Specialised Drugs Program) for all indications for which the reference brand (Neulasta®) is currently PBS-listed. The PBAC advised that Ziextenzo® should be 'a' flagged in the Schedule of Pharmaceutical Benefits with the other brands of pegfilgrastim. The PBAC recommended the addition of an administrative note to encourage the uptake of biosimilar prescribing for treatment-naïve patients, in accordance with the Australian Government's Biosimilar Uptake Driver policy.</p>

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<p>POMALIDOMIDE</p> <p>Capsule 3 mg Capsule 4 mg</p> <p>Pomalyst®</p> <p>Celgene Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Multiple myeloma</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing in combination with bortezomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma (RRMM) who have received at least one prior treatment regimen (including lenalidomide).</p>	<p>The PBAC recommended the Section 100 (Highly Specialised Drug Program) Authority Required listing of pomalidomide, for use in combination with bortezomib and dexamethasone (PBd), for the treatment of patients with RRMM who have been previously treated with lenalidomide. The PBAC noted the strong consumer support and considered that PBd will deliver similar clinical outcomes to carfilzomib and dexamethasone (Cd).</p> <p>The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of PBd would be acceptable if it were cost-minimised to Cd, with the analysis accounting for the differences in adverse events across the treatments.</p> <p>The PBAC considered that the equi-effective doses of PBd and Cd should be equal in terms of treatment duration and relative dose intensity. The PBAC considered that the listing should be cost neutral to the PBS.</p>
<p>PREDNISOLONE ACETATE + PHENYLEPHRINE</p> <p>Eye drops containing prednisolone acetate 10 mg with phenylephrine hydrochloride 1.2 mg per mL, 10 mL</p> <p>Prednefrin® Forte</p> <p>National Aboriginal Community Controlled Health Organisation</p> <p>Change to listing (Minor Submission)</p>	<p>Severe eye inflammation</p>	<p>To request a Restricted Benefit listing for the treatment of severe inflammation of the eye following cataract surgery for patients who identify as Aboriginal and Torres Strait Islander.</p>	<p>The PBAC recommended the Restricted Benefit listing of prednisolone with phenylephrine (Prednefrin® Forte) for severe eye inflammation following cataract surgery for patients who identify as Aboriginal and Torres Strait Islander. In making its recommendation, the PBAC took into consideration, among other matters, the high clinical need of this patient population and that the listing would likely be cost neutral to Government. The recommended listing will allow eligible Aboriginal and Torres Strait Islander people living with chronic disease to access Prednefrin® Forte through the Closing the Gap Copayment Scheme.</p>

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<p>PRIMIDONE</p> <p>Tablet 250 mg</p> <p>APO-Primidone®</p> <p>Apotex Pty Ltd</p> <p>New listing (Other Submission)</p>	<p>Epilepsy</p>	<p>To seek PBAC advice on temporary PBS listing of an alternative brand of primidone 250 mg tablets.</p>	<p>The PBAC recommended the temporary listing of the APO-Primidone® brand to address the current shortage of the PBS-listed Mysoline® brand of primidone.</p>
<p>PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A</p> <p>Oral liquid 125 mL, 24</p> <p>Renastep®</p> <p>Vitaflo Australia Pty Limited</p> <p>New Listing (Minor Submission)</p>	<p>Chronic kidney disease (CKD)</p>	<p>To request an Authority Required (STREAMLINED) listing for the dietary management of paediatric CKD in patients aged 3 years and over who require a modified protein diet.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of protein formula with vitamins and minerals and low in potassium (Renastep®) for the treatment of chronic renal failure for infant and young children on a cost minimisation-basis per calorie of energy equivalent against the cheapest alternative PBS listed whey protein formula indicated for chronic renal failure.</p>

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DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>SALBUTAMOL</p> <p>Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation)</p> <p>Ventolin®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>New Listing (Minor Submission)</p>	<p>Asthma and chronic obstructive pulmonary disease (COPD)</p>	<p>To request an Unrestricted Benefit listing of a new presentation of salbutamol metered dose inhaler with a dose counter (DC).</p>	<p>The PBAC recommended the Unrestricted Benefit listing of salbutamol, in the form of pressurised inhalation 100 micrograms (as sulfate) per dose with a DC, 200 doses (CFC-free formulation). The PBAC's recommendation for listing was based on, among other matters, the potential health benefits related to the likely risk of having sub-therapeutic or negligible drug being available at a time of acute bronchoconstriction and the role of a DC in this specific context to act as a reminder to replace medication. The PBAC considered that the cost-effectiveness of Ventolin DC would be acceptable if it was priced with a small premium over the current Ventolin MDI price.</p>
<p>SEMAGLUTIDE</p> <p>Injection 2 mg in 1.5 mL pre-filled syringe Injection 4 mg in 3 mL pre-filled syringe</p> <p>Ozempic®</p> <p>Novo Nordisk Pharmaceuticals Pty Limited</p> <p>New listing (Major Submission)</p>	<p>Type 2 diabetes mellitus (T2DM)</p>	<p>To request an Authority Required (STREAMLINED) listing for use in combination with metformin and/or a sulfonylurea for the treatment of patients with T2DM.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of semaglutide (injectable) for the treatment of patients with T2DM who have inadequate glycaemic control, as dual therapy in combination with metformin or a sulfonylurea where either of these is contraindicated or not tolerated; or triple therapy in combination with metformin and a sulfonylurea.</p> <p>The PBAC's recommendation for listing was based on a cost-minimisation to dulaglutide.</p>

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<p>TACROLIMUS</p> <p>Capsule 3 mg (once daily prolonged release)</p> <p>Advagraf XL®</p> <p>Astellas Pharma Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Prevention of transplant rejection</p>	<p>To request an unrestricted Benefit listing and a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new form of tacrolimus under the same conditions as the current 500 microgram, 1 mg and 5 mg prolonged-release listings.</p>	<p>The PBAC recommended the Unrestricted Benefit and the Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings of a new form of tacrolimus (3 mg capsule), under the same conditions as the currently listed strengths of tacrolimus and the same price per milligram as the 1 mg capsule.</p>
<p>TEZACAFTOR + IVACAFTOR</p> <p>Tablet containing tezacaftor 100 mg with ivacaftor 150 mg</p> <p>Symdeko®</p> <p>Vertex Pharmaceuticals (Australia) Pty Ltd</p> <p>Change to recommended listing (Minor Submission)</p>	<p>Cystic Fibrosis (CF)</p>	<p>Resubmission to request an extension to the PBAC's March 2019 recommendation for Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of CF in patients aged 12 years or older who have one copy of the F508del mutation and another residual function (RF) mutation in the CF transmembrane conductance regulator (CFTR) gene to be for patients aged 12 years or older who have at least one copy of the RF mutation in the CFTR gene.</p>	<p>The PBAC recommended extending the March 2019 recommendation for the listing of tezacaftor with ivacaftor to include all patients with at least one RF mutation.</p> <p>The PBAC noted that no clinical data for patients with an RF mutation without an F508del mutation in the CFTR gene was available but acknowledged difficulty in obtaining clinical data for these rare CFTR genotypes. The PBAC considered that the incremental benefit of treatment with tezacaftor with ivacaftor compared with best supportive care across all known RF mutations in this patient population is uncertain and therefore, the cost-effectiveness tezacaftor with ivacaftor in this patient population is uncertain. On this basis, the PBAC advised that the additional patients with an RF mutation without an F508del mutation to be treated with tezacaftor with ivacaftor should be included under the current Risk Sharing Arrangement for lumacaftor with ivacaftor and tezacaftor with ivacaftor at no additional cost to Government.</p>

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<p>TOLVAPTAN</p> <p>Tablets 15 mg Tablets 30 mg 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</p> <p>Jinarc®</p> <p>Otsuka Australia Pharmaceutical Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Autosomal dominant polycystic kidney disease (ADPKD)</p>	<p>To request:</p> <ul style="list-style-type: none"> • listing of two new forms (15 mg and 30 mg tablets) of tolvaptan for the treatment of patients with ADPKD; • to change the current General Schedule listings of tolvaptan to Section 100 (Highly Specialised Drugs Program - Community Access); and • to change the authority level for initial treatment from a written to telephone authority. 	<p>The PBAC recommended the listing of two new forms of tolvaptan for the treatment of ADPKD, on a cost-minimisation basis and under the same conditions as current listings, to improve dose flexibility for patients requiring dose modification. The PBAC also recommended amending the authority level for initial treatment from a written authority to telephone/electronic authority, as the restriction criteria are not complex.</p> <p>The PBAC did not recommend the request to amend the listings of tolvaptan to Section 100 (Highly Specialised Drugs Program (HSD) – Community Access), as it did not consider the administration or patient monitoring requirements for tolvaptan were sufficiently complex to consider the drug to be highly specialised. The PBAC noted that in general drugs in the Section 100 HSD – Community Access stream have been limited to continuation therapy for patients who have commenced treatment in a hospital setting. The PBAC considered that given there was no clinical need for patients to receive initial treatment with tolvaptan in a hospital setting, the requested change to the program was not adequately justified.</p>
<p>TRASTUZUMAB</p> <p>Powder for I.V. infusion 60 mg Powder for I.V. infusion 150 mg</p> <p>Trazimera®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Human epidermal growth factor receptor-2 (HER2) positive breast cancer</p> <p>HER positive gastric cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of the biosimilar brand of trastuzumab (Trazimera®), for all indications for which the reference brand Herceptin® is currently PBS listed.</p> <p>The PBAC noted that Efficient Funding of Chemotherapy medicines are governed by the <i>National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011</i>, and that Section 33(2) allows substitution of brands under the same item code.</p>

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<p>TRASTUZUMAB EMTANSINE</p> <p>Powder for I.V. infusion 100 mg Powder for I.V. infusion 160 mg</p> <p>Kadcyla®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Early breast cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the adjuvant treatment of patients with Human epidermal growth factor receptor-2 positive (HER2+) early breast cancer with residual disease following neoadjuvant treatment with HER2-targeted therapy.</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required listing of trastuzumab emtansine for the treatment of adjuvant therapy of patients with HER2+ early breast cancer with residual disease following HER2-targeted neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy. The PBAC acknowledged the high clinical need of patients in this population.</p> <p>The PBAC was satisfied that trastuzumab emtansine provides, for some patients, a significant improvement in invasive disease-free survival over trastuzumab. Although the data for overall survival were immature, the PBAC considered that there was moderate certainty that the invasive disease-free survival benefits would translate into overall survival benefits based on the KATHERINE trial data. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of trastuzumab emtansine over trastuzumab was within an acceptable range.</p>
<p>TRIFLURIDINE + TIPIRACIL</p> <p>Tablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride) Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride)</p> <p>Lonsurf®</p> <p>Servier Laboratories (Aust.) Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Gastric cancer</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with metastatic gastric cancer who have been previously treated with, or are not considered candidates for, currently available therapies.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of trifluridine/tipiracil, in fixed dose combinations, for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction previously treated with at least two prior lines of chemotherapy.</p> <p>The PBAC acknowledged that there is a high and unmet clinical need for additional therapies for patients with refractory metastatic gastric adenocarcinoma and good performance status. The PBAC was satisfied that trifluridine/tipiracil, for some patients, provides some improvement in overall survival over best supportive care, which needs to be balanced against an increase in toxicity. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of trifluridine/tipiracil would be acceptable at the price proposed in the submission.</p>

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<p>UPADACITINIB</p> <p>Tablet (modified release) 15 mg</p> <p>Rinvoq®</p> <p>AbbVie Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Rheumatoid arthritis (RA)</p>	<p>To request an Authority Required listing for the treatment of patients with severe active RA.</p>	<p>The PBAC recommended the listing of upadacitinib for the treatment of RA on a cost-minimisation basis to the least costly biological disease modifying anti-rheumatic drug listed on the PBS for RA.</p>