

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|-------------------------|--|---|
| <p>ADRENALINE</p> <p>I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector</p> <p>I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector</p> <p>Emerade®</p> <p>Link Medical Products Pty Ltd</p> <p>New listing (Other Submission)</p> | <p>Anaphylaxis</p> | <p>To request a temporary Authority Required listing for the treatment of anaphylaxis.</p> | <p>The PBAC recommended the temporary listing of Emerade (adrenaline 300 mcg and 150 mcg auto-injectors) to address the current shortage issue of PBS-listed EpiPen and EpiPen Junior until 31 August 2018.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|---|--|---|
| <p>1) AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE 2) AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE 3) AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE</p> <p>Oral liquid 87 mL, 30; Oral liquid 130 mL, 30; and Oral liquid 174 mL, 30</p> <p>1) MSUD cooler 10, 15 and 20; 2) TYR cooler 10, 15 and 20; and 3) HCU cooler 10, 15 and 20</p> <p>Vitaflo Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>1)Maple Syrup Urine Disease (MSUD) 2)Tyrosinaemia (TYR) 3)Homocystinuria (HCU)</p> | <p>To request changes to the Restricted Benefit listings of MSUD, TYR and HCU Coolers including nutritional content.</p> | <p>The PBAC recommended the changes to the Restricted Benefit listing of MSUD, TYR and HCU Coolers to make minor changes to the nutritional content for these formulations.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|--|--|---|
| <p>A POMORPHINE</p> <p>Solution for subcutaneous infusion containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen</p> <p>Movapo Pen</p> <p>Stada Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Parkinson disease</p> | <p>To request a Section 100 (Highly Specialised Drugs Program - Public and Private Hospital) listing of a new form of apomorphine.</p> | <p>The PBAC recommended the Authority Required listing of a new form of apomorphine (30 mg in 3 mL) delivered in a disposable multiple dose pen injector system for the treatment of Parkinson's disease, on the basis that it should be available under Section 100 Highly Specialised Drugs (HSD) Program.</p> |
| <p>BARICITINIB</p> <p>Tablet 2 mg Tablet 4 mg</p> <p>Olumiant®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Severe active rheumatoid arthritis (RA)</p> | <p>Resubmission to request an Authority Required listing for the treatment of severe active RA under certain conditions.</p> | <p>The PBAC recommended the listing of baricitinib for the treatment of rheumatoid arthritis on a cost-minimisation basis against the least costly biological Disease Modifying Anti-Rheumatic Drug (bDMARD).</p> |
| <p>BENRALIZUMAB</p> <p>30mg in 1 mL solution for injection prefilled syringe</p> <p>Fasenra®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Major Submission)</p> | <p>Uncontrolled severe eosinophilic asthma</p> | <p>To request a Section 100 (Highly Specialised Drug Program) Authority Required listing for the treatment of uncontrolled severe eosinophilic asthma.</p> | <p>The PBAC recommended the Section 100 (Highly Specialised Drug Program) Authority required (in writing) listing of benralizumab for the treatment of uncontrolled severe eosinophilic asthma in patients aged 12 years and over. In making this recommendation, the PBAC noted the clinical need for additional treatment options in uncontrolled severe asthma.</p> <p>The PBAC recommended the listing on a cost-minimisation basis with mepolizumab. The PBAC considered that the estimation of equi-effective doses should include the fixed loading doses of benralizumab, which would be consistent with methods used to estimate the equi-effective doses of other biologics (in other conditions) that require fixed loading doses.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--|---|---|
| <p>BENRALIZUMAB</p> <p>30mg in 1 mL solution for injection prefilled syringe</p> <p>Fasenra®</p> <p>AstraZeneca Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>Uncontrolled severe eosinophilic asthma</p> | <p>To request amendments to the current Section 100 (Highly Specialised Drugs Program - Public and Private Hospital) restrictions for uncontrolled severe eosinophilic asthma.</p> | <p>The PBAC recommended changing the restriction for biologics for severe asthma to reduce the duration of time that a patient must be under the care of the same physician from 12 months to six months. The PBAC considered that this change may improve continuity of care and access to effective treatment when patients with uncontrolled severe asthma change physicians.</p> <p>The PBAC noted that the submission's request to extend the eosinophil blood test validity period had already been addressed, pursuant to a positive recommendation for mepolizumab that was made at the Committee's November 2017 meeting. The PBAC considered that this adequately addressed the submission's request to change the time period for validity of this test.</p> <p>The PBAC deferred making a decision on the request to remove the six month treatment break when switching between different biologics. The PBAC considered that removal of the treatment break would have flow-on implications and would require consideration of issues around re-trialling of the same biologic, switching between and cycling of biologics in asthma. The PBAC's deferral of its decision was to enable further consideration and broader discussion given the complexity of these matters.</p> |
| <p>CARFILZOMIB</p> <p>Powder for I.V. infusion 10 mg</p> <p>Kyprolis®</p> <p>Amgen Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Multiple myeloma</p> | <p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for a new lower strength form of carfilzomib in combination with dexamethasone for the treatment of patients with multiple myeloma who have failed at least one prior line of treatment.</p> | <p>The PBAC recommended the listing of a 10 mg vial form of carfilzomib as a Section 100 – Efficient Funding of Chemotherapy benefit on the basis of the same cost per mg and restriction conditions as the currently listed 30 and 60 mg vial forms for the treatment of multiple myeloma.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|---|---|---|
| <p>CETUXIMAB</p> <p>Solution for I.V. infusion 100 mg in 20 mL Solution for I.V. infusion 500 mg in 100 mL</p> <p>Erbix®</p> <p>Merck Serono Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p> | <p>Recurrent or metastatic squamous cell carcinoma of the head and neck</p> | <p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck.</p> | <p>The PBAC recommended listing of cetuximab for the treatment of patients with previously untreated recurrent and/or metastatic squamous cell carcinoma of the head and neck, on the basis that it should be available only under special arrangements under section 100. The PBAC was satisfied of the clinical need in this patient population and that, for some patients, cetuximab provides a modest improvement in overall survival, progression free survival and response rates over chemotherapy alone. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost effectiveness of cetuximab could be brought into an acceptable range with a reduced effective price.</p> |
| <p>DEXAMETHASONE</p> <p>Intravitreal injection 700 micrograms</p> <p>Ozurdex®</p> <p>Allergan Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p> | <p>Macular oedema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).</p> | <p>To request an Authority Required listing for the treatment of macular oedema secondary to BRVO and CRVO.</p> | <p>The PBAC recommended extending the listing of dexamethasone intravitreal injection 700 micrograms (dexamethasone implant) as an Authority required benefit (in writing for initial and telephone for continuing treatment) for patients with central or branch retinal vein occlusion (RVO) who have failed or are contraindicated to vascular endothelial growth factor (VEGF) inhibitors. This recommendation was based on clinical need, acceptable clinical effectiveness compared to placebo, and the broader context of the existing listing of dexamethasone for diabetic macular oedema. The clinical trial data for dexamethasone implant compared with placebo showed a modestly improved benefit with dexamethasone implant for some patients (a difference of between 6 to 9 gain in letters in best corrected visual acuity over placebo at 2 months), with the efficacy of the dexamethasone implant waning beyond month 3.</p> <p>The PBAC did not recommend extending the listing to patients with RVO who are considered 'unsuitable' for VEGF inhibitors, due to the ambiguity of the proposed restriction wording leading to potential use of an inferior and more harmful therapy than a VEGF inhibitor, based primarily on convenience. The clinical need for an alternative therapy for patients who may respond to a VEGF inhibitor but in whom monthly injections may be difficult, was not adequately supported to make available a sub-optimal therapy for a generally short-term condition.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--|--|--|
| <p>1) ERTUGLIFLOZIN 2) ERTUGLIFLOZIN WITH METFORMIN</p> <p>1) Tablet containing 5 mg ertugliflozin; Tablet containing 15 mg ertugliflozin 2) Tablet containing 2.5 mg ertugliflozin with 500 mg metformin hydrochloride; Tablet containing 2.5 mg ertugliflozin with 1 g metformin hydrochloride; Tablet containing 7.5 mg ertugliflozin with 500 mg metformin hydrochloride; Tablet containing 7.5 mg ertugliflozin with 1 g metformin hydrochloride;</p> <p>1) Steglatro® 2) Segluromet®</p> <p>Merck Sharp & Dohme (Australia) 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 dual oral combination therapy for patients with T2DM who are inadequately controlled with metformin or a sulfonylurea.</p> | <p>The PBAC recommended the Authority Required (STREAMLINED) listing of the 5 mg dose strength ertugliflozin for dual oral therapy with metformin or a sulfonylurea, and the 2.5 mg ertugliflozin with 500 mg metformin and 2.5 mg ertugliflozin with 1 g metformin fixed dose combinations (FDC), for the treatment of T2DM on a cost-minimisation basis to dapagliflozin and empagliflozin.</p> <p>The PBAC considered that the evidence presented in the submission supported a claim of non-inferior efficacy and safety for ertugliflozin compared to dapagliflozin or empagliflozin. The equi-effective doses are ertugliflozin 5 mg (once daily) and dapagliflozin 10 mg or empagliflozin 10 mg or 25 mg (once daily). The equi-effective doses for the FDC were considered to be equivalent to the same dose of individual components taken concomitantly.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|---|---|--|
| <p>ETANERCEPT</p> <p>Injection 50 mg in 1 mL single use auto-injector, 4 Injection 50 mg in 1 mL single use pre-filled syringes, 4</p> <p>Erelzi®</p> <p>Sandoz Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Rheumatoid arthritis (RA), psoriatic arthritis (PsA), plaque psoriasis, ankylosing spondylitis, juvenile idiopathic arthritis (JIA), paediatric plaque psoriasis</p> | <p>To request an Authority Required listing for the same indications as the reference biologic.</p> | <p>The PBAC recommended the listing of the Erelzi brand of etanercept for the same indications as the reference brand Enbrel, including juvenile idiopathic arthritis (JIA) and juvenile plaque psoriasis (JPP). In making this recommendation, the PBAC noted the TGA Advisory Committee for Medicines (ACM) has declared Erelzi to be a biosimilar of the reference brand, Enbrel. The PBAC advised the Minister that, under Section 101(4AACD) of the National Health Act, 1953 the Erelzi, Brenzys and Enbrel brands of etanercept could be marked as equivalent ('a' flagged) in the Schedule of Pharmaceutical Benefits.</p> <p>The PBAC considered it was appropriate for biosimilar uptake drivers to be applied to this brand of etanercept and the listings for Erelzi should align with the current listings for the Brenzys brand of etanercept for the adult indications (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis), and include a streamlined authority listing for subsequent continuing prescribing and include a note in the restriction regarding biosimilar uptake.</p> <p>With regards to the juvenile indications (JIA and JPP), the PBAC noted the Brenzys brand was not listed for these indications and no biosimilars are PBS listed for these indications. The PBAC noted the Erelzi brand was TGA registered for these indications and recommended that similar to the adult indications, the restrictions for JIA and JPP be remodelled to facilitate the application of biosimilar uptake drivers to these Erelzi listings.</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 Limited</p> <p>Change to listing (Minor Submission)</p> | <p>Familial hypercholesterolaemia (FH)</p> | <p>Resubmission to request an Authority Required listing for treatment of patients with FH who have either very high LDL-c or symptomatic atherosclerotic cardiovascular disease (ASCVD).</p> | <p>The PBAC recommended extending the PBS listing for evolocumab for patients with Familial Hypercholesterolaemia (FH) to include patients with heterozygous FH, under certain conditions. The PBAC accepted that both the heterozygous and homozygous FH populations are high risk, and that the use of evolocumab could be extended to include the heterozygous population as it would be an effective and safe therapy following failed treatment with statins and ezetimibe. The PBAC considered that the revised economic model, reduced price and other arrangements proposed in the resubmission addressed the outstanding issues raised by the PBAC from the November 2017 submission.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--|---|---|
| <p>FOLLITROPIN ALFA</p> <p>Injection 75 I.U. in 0.125 mL pre-filled pen Injection 150 I.U. in 0.25 mL pre-filled pen Injection 225 I.U. in 0.375 mL pre-filled pen Injection 300 I.U. in 0.5 mL pre-filled pen Injection 450 I.U. in 0.75 mL pre-filled pen</p> <p>Bemfola®</p> <p>Gedeon Richter Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>Assisted Reproductive Technology (ART); Anovulatory infertility; Infertility due to hypogonadotropic hypogonadism</p> | <p>To request that the current listings of Bemfola be changed to a Restricted Benefit (for the Section 100 IVF listings), and to include a NOTE encouraging prescribing for treatment-naïve patients.</p> | <p>The PBAC recommended the addition of an administrative advice to the PBS listings for all Gonalf® items to encourage prescribing of biosimilar brands for treatment naïve patients</p> <p>The PBAC did not recommend lowering the category of prescribing authority for Bemfola®. In deciding not to recommend a change to the current Authority Required (STREAMLINED) category of prescribing authority for Bemfola® for Assisted Reproductive Technology, the PBAC considered;</p> <ul style="list-style-type: none"> • The potential for prescriber confusion surrounding Restricted Benefit listings for other infertility indications, which have differing maximum quantities and number of repeats; • Changing the prescribing authority to Restricted Benefit would be inconsistent with other follitropins currently listed as Authority Required in the Section 100 IVF Program for Assisted Reproductive Technology; and • No apparent benefit in terms of driving uptake of Bemfola®, given the current category of prescribing authority is STREAMLINED |
| <p>HYDROMORPHONE</p> <p>Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL</p> <p>Dilaudid®</p> <p>Mundipharma Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Severe disabling pain</p> | <p>To request a Restricted Benefit listing for the treatment of severe disabling pain.</p> | <p>The PBAC recommended the listing of a 200 mL PET bottle replacement, containing hydromorphone hydrochloride, for the currently listed 473 mL glass bottle Dilaudid® Oral Liquid presentation indicated for use in severe disabling pain. The PBAC considered the listing of a 200 mL presentation of Dilaudid® Oral Liquid to be appropriate. The PBAC noted that a reduction in the volume of opioid available in the community at any one time may be a positive outcome from a quality use of medicines perspective.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|---|---|--|
| <p>IBRUTINIB</p> <p>Capsule 140 mg</p> <p>Imbruvica®</p> <p>Janssen-Cilag Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>Chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL) and relapsed or refractory mantle cell lymphoma (MCL)</p> | <p>Resubmission to request an Authority Required listing for the first line treatment of patients with CLL or SLL who meet certain criteria and relapsed or refractory MCL.</p> | <p>The ibrutinib submission requested listing for two conditions: relapsed or refractory mantle cell lymphoma; and first-line treatment of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL). A single submission was made as a combined risk sharing arrangement (RSA) was proposed to cover both indications.</p> |
| | | <p>Current PBS listing Relapsed/refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p> | <p>Mantle cell lymphoma (recommended) The PBAC recommended extending the PBS-listing of ibrutinib as an Authority Required benefit to include the treatment of patients with relapsed/refractory mantle cell lymphoma. The PBAC considered that the cost-effectiveness of ibrutinib in relapsed/refractory mantle cell lymphoma was acceptable at the price applied in the economic model. The recommendation reflected the high clinical need in a condition that affects a small number of patients.</p> |
| | | | <p>First-line chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) (Not Recommended) The PBAC did not recommend the listing of ibrutinib for the treatment of first-line CLL/SLL on the basis of (i) uncertain cost-effectiveness given the pricing arrangements proposed and (ii) overestimated financial estimates. The PBAC noted that the cost of ibrutinib used in the economic model, and thus the ICER, relied on RSA rebates. The PBAC considered it was unlikely that the RSA rebates would be achieved and therefore it was unlikely that acceptable cost effectiveness would be realised, as the utilisation underpinning the RSA was significantly overestimated. This was because the patient numbers, uptake rate and compliance rate were overestimated.</p> <p>The PBAC noted that updated clinical data for progression free survival were available but had not been incorporated into the economic model. The PBAC considered that this would be informative given the economic model's reliance on progression free survival and extrapolated data, and the considerably longer duration of follow-up available with the new data.</p> <p>For the first-line CLL or SLL aspects of the resubmission:</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME | |
|-----------------------------------|------------------|--|--|---|
| | | | Comparator: rituximab plus chlorambucil | Accepted. |
| | | | Clinical claim: Superior comparative efficacy and non-inferior safety compared with rituximab plus chlorambucil. | Accepted. However the PBAC noted that emerging data suggest that there is an increased risk of atrial fibrillation associated with ibrutinib. |
| | | | Economic claim: Cost-utility analysis compared with rituximab plus chlorambucil | Not accepted, as outlined above. |
| | | | Sponsor's comments: Janssen is disappointed with the outcome for ibrutinib in first line CLL and are currently assessing our position. | |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|---|--|---|
| <p>INACTIVATED INFLUENZA VACCINE (SURFACE ANTIGEN), ADJUVANTED</p> <p>Injection 0.5 mL in pre-filled syringe</p> <p>Fluad®</p> <p>Seqirus (Australia) Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Prevention of seasonal influenza</p> | <p>To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.</p> | <p>The PBAC recommended that inactivated trivalent influenza vaccine (surface antigen), adjuvanted (aTIV) vaccine be a designated vaccine for the purposes of the <i>National Health Act 1953</i> for active immunisation against influenza in adults aged ≥65 years of age.</p> <p>The PBAC considered that the aTIV vaccine would be acceptably cost-effective if subsidised on a cost-minimisation basis with the currently NIP listed quadrivalent inactivated vaccines (QIV) for those aged ≥65.</p> <p>The PBAC agreed with the Australian Technical Advisory Group on Immunisation (ATAGI) that there is sufficient evidence indicating aTIV is superior in effectiveness to non-adjuvanted trivalent inactivated vaccine (TIV) in some scenarios, particularly in seasons dominated by influenza A/H3 disease which accounts for a substantial burden in this age group.</p> <p>The PBAC also agreed with the ATAGI that the potential additional protection afforded by aTIV against the strains included in the vaccine is substantial enough to offset, if not outweigh, the potential loss of protection against the alternative B lineage not in the QIV vaccine, in most years, for adults aged ≥65 years.</p> <p>The PBAC noted that the submission had been made on a cost-minimisation basis to the current standard of care (QIV) in response to liaison with the company from the Chief Medical Officer to contribute to the Government's response to public health concerns around the 2018 influenza season.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|---|--|--|
| <p>INACTIVATED TRIVALENT INFLUENZA VACCINE (SPLIT VIRION)</p> <p>Injection 0.5 mL in pre-filled syringe</p> <p>Fluzone® High-Dose</p> <p>Sanofi-aventis Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Prevention of seasonal influenza</p> | <p>To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.</p> | <p>The PBAC recommended that inactivated trivalent influenza vaccine (TIV-HD) be a designated vaccine for the purposes of the <i>National Health Act 1953</i> for active immunisation against influenza in adults aged ≥65 years.</p> <p>The PBAC considered that the TIV-HD vaccine would be acceptably cost-effective if subsidised on a cost-minimisation basis with the currently NIP listed quadrivalent inactivated vaccines (QIV) for those aged ≥65.</p> <p>The PBAC agreed with the Australian Technical Advisory Group on Immunisation (ATAGI) that there was sufficient evidence indicating TIV-HD is superior in effectiveness to a standard-dose trivalent inactivated vaccine (TIV-SD) against vaccine-matched influenza strains. The PBAC also agreed with the ATAGI that the additional protection against vaccine-matched strains included in the TIV-HD vaccine is substantial enough to offset, if not outweigh, the potential loss of protection against the alternative B lineage not in the vaccine, in most years, for adults aged ≥65 years.</p> <p>The PBAC noted that the submission had be made on a cost-minimisation basis to the current standard of care (QIV) in response to liaison with the company from the Chief Medical Officer to contribute to the Government’s response to public health concerns around the 2018 influenza season. The PBAC noted the sponsor’s advice that it intended make a further submission for a cost-effectiveness claim.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|------------------------------|---|---|
| <p>INSULIN DEGLUDEC WITH INSULIN ASPART</p> <p>Injections, cartridges, 70 units-30 units per mL, 3 mL, 5 Injections, pre-filled pen, 70 units-30 units per mL, 3 mL, 5</p> <p>Ryzodeg FlexTouch® Ryzodeg Penfill®</p> <p>Novo Nordisk Pharmaceuticals Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Diabetes mellitus</p> | <p>Resubmission to request an unrestricted listing to improve glycaemic control in adult patients with diabetes mellitus where basal and prandial insulin treatment is necessary.</p> | <p>The PBAC recommended the unrestricted listing of insulin degludec with insulin aspart (IDegAsp) for treatment of adult patients with diabetes mellitus where insulin treatment is necessary. The PBAC accepted biphasic insulin aspart (BIAsp 30) as the appropriate comparator for IDegAsp in type 1 (T1) and type 2 diabetes mellitus (T2DM) populations. The PBAC reaffirmed that the claim of non-inferior comparative effectiveness was reasonably supported by the data. The PBAC considered that it was appropriate that no benefit claim for reduced hypoglycaemia was made in the modelled cost-minimisation analysis in the resubmission. The PBAC considered that the remaining uncertainties were addressed by the reduction in price for IDegAsp in the resubmission.</p> |
| <p>MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE</p> <p>Injection 0.5 mL in pre-filled syringe</p> <p>Nimenrix®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Major Submission)</p> | <p>Meningococcal disease</p> | <p>To request listing on the National Immunisation Program (NIP) for the active immunisation of infants.</p> | <p>The PBAC recommended that meningococcal polysaccharide serogroups A, C, W135 and Y conjugate vaccine (MenACWY-TT) vaccine be a designated vaccine for the purposes of the <i>National Health Act 1953</i> for the prevention of invasive meningococcal disease (IMD) caused by <i>Neisseria meningitidis</i> serogroups A, C, W135, and Y (MenA, MenC, MenW135 and MenY, respectively) in infants.</p> <p>In line with the Australian Technical Advisory Group on Immunisation (ATAGI) advice, the PBAC recommended that the administration of the MenACWY-TT vaccine occur at around 12 months of age and further that administration of the haemophilus influenzae Type B (hib) containing vaccine be moved to around 18 months of age.</p> <p>The PBAC considered the MenACWY-TT vaccine would be acceptably cost-effective if subsidised on a cost-minimisation basis with the MenC component of the Hib-MenC vaccine (Menitorix).</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|------------------------------|--|--|
| <p>MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE</p> <p>Injection 0.5 mL in pre-filled syringe</p> <p>Nimenrix®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Major Submission)</p> | <p>Meningococcal disease</p> | <p>To request listing on the National Immunisation Program (NIP) for the immunisation of adolescents in Year 10 and a catch-up program for adolescents aged up to 19 years administered via a school or GP-based catch up program.</p> | <p>The PBAC recommended that meningococcal polysaccharide serogroups A, C, W135 and Y conjugate vaccine (MenACWY-TT) be a designated vaccine for the purposes of the <i>National Health Act 1953</i> for the prevention of invasive meningococcal disease (IMD) caused by <i>Neisseria meningitidis</i> serogroups A, C, W135, and Y (MenA, MenC, MenW135 and MenY, respectively) in adolescents as part of a school based immunisation program for year 10 students (aged 14-16) and via a catch-up program for adolescents aged up to 19 years old.</p> <p>The PBAC noted the limitations of the available clinical evidence including the use of single-arms of randomised trials which do not take into account rates of natural immunity, as well as the lack of studies measuring nasopharyngeal meningococcal carriage rates to assess the potential for herd immunity. The PBAC considered that the clinical claim of superior efficacy compared with no vaccine was reasonable. However, the PBAC noted the impact of vaccination on the population incidence of IMD was highly uncertain. The PBAC considered that overall, the MenACWY-TT vaccine had a reasonable safety profile and whilst inferior to the comparator of no vaccine, the adverse events were generally mild or moderate.</p> <p>The PBAC considered the cost-effectiveness of the MenACWY-TT vaccine to be uncertain given the requirement to translate serological outcomes to clinical outcomes of avoidance of invasive meningococcal disease and associated deaths, and that the assumed extent of herd immunity was a key driver of the result. The PBAC recommended the NIP listing of the MenACWY-TT vaccine contingent upon a price reduction such that the incremental cost-effectiveness ratio is less than \$15,000 per quality adjusted life year gained.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|----------------------------|---|---|
| <p>NICOTINE</p> <p>Gum 2 mg Gum 4 mg Lozenge 2 mg Lozenge 4 mg</p> <p>Nicotinell Chewing gum® Nicotinell lozenge®</p> <p>Orion Laboratories Pty Ltd T/A Perrigo Australia</p> <p>New listing (Other Submission)</p> | <p>Nicotine dependence</p> | <p>To request a Restricted Benefit listing for nicotine chewing gum and lozenges to aid smoking cessation in patients with nicotine dependence.</p> | <p>The PBAC recommended the listing of nicotine gum and lozenge, as monotherapies on the PBS as a restricted benefit for treating nicotine dependence in cigarette smokers who wish to quit and enter into a behavioural support program. The PBAC had previously accepted the submission’s overall claim of non-inferiority in terms of comparative efficacy and safety for nicotine gum and lozenges compared with nicotine patches in July 2017, but deferred its decision at that time due to uncertainty in the estimation of equi-effective doses against the comparator, nicotine patches. The PBAC considered that the revised approach taken by the submission to calculate the equi-effective doses suitably addressed this uncertainty.</p> <p>In its July 2017 consideration the PBAC noted that the efficacy of nicotine lozenges and gum significantly improved when used in combination with nicotine patches, but that no evidence was provided in the submission about the cost-effectiveness of combination treatment. However the PBAC considered that further clinical evidence and utilisation estimates were warranted before the comparative efficacy and cost-effectiveness of combination use could be appropriately determined by the Committee.</p> <p>The PBAC acknowledged that its recommendation for the listing of nicotine gum and lozenges as monotherapies (as is the case for nicotine patches subsidised through the PBS) is not consistent with the latest clinical guidelines, which encourage health professionals to consider recommending the use of combination nicotine replacement therapy. The PBAC reiterated that in the absence of evidence about the cost-effectiveness of combination treatment it is not possible to further an assessment of combination treatment at the present time in the context of this submission. However the PBAC considered that a broader review of PBS-subsidised nicotine dependence treatments in the context of the current clinical guidelines would be informative to whether current subsidy arrangements could better achieve the intended purpose of supporting smoking cessation.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| 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 (Minor Submission)</p> | <p>Squamous cell carcinoma for the head and neck (SCCHN)</p> | <p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with squamous cell carcinoma of the head and neck (SCCHN) who progress within 6 months following platinum-based therapy.</p> | <p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy - Public and Private Hospital) Authority Required (STREAMLINED) listing of nivolumab for the treatment of squamous cell carcinoma of the head and neck. In making this recommendation, the PBAC considered the high unmet clinical need in an aggressive and debilitating malignancy and advised that nivolumab treatment resulted in modest yet meaningful clinical benefit for some patients.</p> |
| <p>NUSINERSEN</p> <p>Solution for injection 12 mg in 5 mL</p> <p>Spinraza™</p> <p>Biogen Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Treatment of infantile-onset (Type I) spinal muscular atrophy (SMA)</p> | <p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of Type I SMA.</p> | <p>The PBAC recommended the Section 100 (Highly Specialised Drugs Program) listing of nusinersen for the treatment of Type I, II and IIIa spinal muscular atrophy (SMA) in patients 18 years of age or under at initiation of treatment, who had onset of signs and symptoms consistent with SMA prior to 3 years of age. The PBAC reaffirmed the high clinical need for new treatments for SMA and considered that based on the information presented at the nusinersen stakeholder meeting, paediatric patients with symptom onset before the age of 3 years are those in highest need of treatment due to the severity of their condition. The PBAC considered that the economic analyses presented in the submission were more informative of the cost-effectiveness of treatment with nusinersen for SMA compared with the analyses presented in November 2017. The PBAC considered that while the price reduction proposed was substantial, it did not fully address the PBAC's concerns regarding the uncertainty of the extent and durability of treatment effect. The PBAC advised that further negotiations with the sponsor would be required to for a cost-effective listing to proceed.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--|---|--|
| <p>OLAPARIB</p> <p>Tablet 100 mg Tablet 150 mg</p> <p>Lynparza®</p> <p>AstraZeneca Pty Ltd</p> <p>New listing (Major Submission)</p> | <p>High-grade serous ovarian, fallopian tube and primary peritoneal cancer</p> | <p>To request an Authority Required listing for the treatment of high-grade serious ovarian, fallopian tube and primary peritoneal cancer.</p> | <p>The PBAC recommended the Authority Required (General Schedule) listing of a new tablet form of olaparib for the treatment of recurrent platinum-sensitive high grade serous ovarian, fallopian tube and primary peritoneal cancers with documented germline class 4 or 5 BRCA 1 or BRCA2 gene mutation, on a cost-minimisation basis to olaparib capsules. In making this recommendation, the PBAC noted that the sponsor intended to withdraw the capsule form of this medicine from the market and acknowledged that the new form represented a reduced pill burden for patients. The PBAC advised that a reduction in price would be required for the listing to be cost neutral to the Commonwealth at the equi-effective doses recommended by the Committee.</p> |
| <p>OMALIZUMAB</p> <p>Injection 150 mg in 1 mL single dose pre-filled syringe</p> <p>Xolair®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>Severe chronic spontaneous urticaria</p> | <p>To request a General Schedule Authority Required listing for the treatment of severe chronic spontaneous urticaria in addition to the current Section 100 (Highly Specialised Drug) listing.</p> | <p>The PBAC recommended a Section 85 (S85) Authority Required (Written) and Authority Required (Telephone) listing of omalizumab for the initial and continuing treatment respectively, for patients with severe chronic spontaneous urticaria (CSU), in addition to the existing Section 100 Highly Specialised Drugs (S100 HSD) Authority Required listings for CSU. In making this recommendation, the PBAC noted that it would improve access for patients whose initial consultation is with a non-hospital affiliated physician who cannot prescribe omalizumab under S100, but would be able to do so under S85. The PBAC advised that the sponsor would need to reduce the ex-manufacturer price of omalizumab to ensure that the impact to government would remain cost neutral for the dual S85 and S100 listings.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|--|--|--|
| <p>PALBOCICLIB</p> <p>Capsule 75 mg Capsule 100 mg Capsule 125 mg</p> <p>Ibrance®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer</p> | <p>Resubmission to request an Authority Required listing as initial endocrine-based therapy in patients with HR+, HER2-locally advanced, inoperable or metastatic breast cancer in combination with a non-steroidal aromatase inhibitor.</p> | <p>The PBAC recommended the listing of palbociclib in combination with a non-steroidal aromatase inhibitor (NSAI) (letrozole or anastrozole) as initial endocrine-based therapy in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced inoperable or metastatic breast cancer. The PBAC was satisfied that for some patients, palbociclib in combination with an NSAI provides additional progression free survival compared with an NSAI alone, though its effect on overall survival is unknown. The PBAC noted that if overall survival was not improved by treatment with palbociclib then the observed gain in progression free survival would be at the expense of a reduced time spent in the post-progression state. In this context, the modelled cost-effectiveness was considered uncertain, but the Committee considered that the modelled cost effectiveness of palbociclib could be brought into an acceptable range with a reduced effective price in conjunction with financial caps.</p> <p>The PBAC considered ribociclib an appropriate near market comparator. The PBAC noted that there are limited data to support the clinical claim for palbociclib compared with ribociclib but considered that the claim of non-inferior clinical effectiveness and safety appears reasonable.</p> |
| <p>PEGFILGRASTIM</p> <p>Injection 6 mg in 0.6 mL single use pre-filled syringe</p> <p>Neulasta®</p> <p>Amgen Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>Prophylaxis of chemotherapy induced neutropenia</p> | <p>To request a Section 100 (Highly Specialised Drug) Authority Required listing for the treatment of patients for primary prophylaxis of chemotherapy induced neutropenia in patients with early stage breast cancer in patients receiving docetaxel and cyclophosphamide based chemotherapy.</p> | <p>The PBAC recommended the expanded listing of pegfilgrastim, on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals) for patients receiving chemotherapy treatment with the intention of achieving a cure or substantial remission, as primary prophylaxis where the chemotherapy treatment carries a risk of febrile neutropenia (FN) or prolonged severe neutropenia greater than 20%, and as secondary prophylaxis for patients who have had an episode of FN or prolonged severe neutropenia.</p> <p>The PBAC advised that the restriction changes could also be applied to filgrastim and lipegfilgrastim, pending agreement from the relevant sponsors to the expanded listing and associated pricing consequences.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--------------------------------|--|--|
| <p>PEMBROLIZUMAB</p> <p>Powder for injection 50 mg Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck, Sharp and Dohme (Australia) Pty Limited</p> <p>Change to listing (Minor Submission)</p> | <p>Melanoma</p> | <p>To request a change to the dosing regimen to a fixed dose, from weight-based dosing, with a new maximum amount.</p> | <p>The PBAC recommended an amendment to the existing PBS restrictions for the treatment of unresectable Stage III or Stage IV malignant melanoma, to allow either a weight-based dose of 2 mg/kg or a fixed dose of 200 mg, every three weeks. The PBAC recommended that the maximum amount be adjusted to 200 mg.</p> <p>The PBAC noted that the sponsor requested a change in dosing from being weight based to fixed. The PBAC considered that the change in dosing has the effect of wasting on average 25% of the drug because the fixed dosing results in a higher administered dose without any additional patient benefit. For this reason, the PBAC concluded that a change from the weight-based to fixed dose regimen would not be cost-effective on a per-patient basis, as currently the mean dose of pembrolizumab is significantly less than 200 mg. However, the PBAC noted that there is currently a relevant risk sharing arrangement in place. The PBAC therefore advised that subsequent annual expenditure caps for this melanoma-based Deed of Agreement should be negotiated with the sponsor for pembrolizumab based on the weight-based dosing regimen, to ensure that the PBS listing remains acceptably cost-effective.</p> |
| <p>PERFLUOROHEXYLOCTANE</p> <p>Eye drops containing perfluorohexyloctane, 3 mL</p> <p>NovaTears®</p> <p>AFT Pharmaceuticals Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Severe dry eye syndrome</p> | <p>To request an Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome.</p> | <p>The PBAC recommended a General Schedule and an Optometric Schedule Authority Required (STREAMLINED) listing of perfluorohexyloctane for the treatment of severe dry-eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--------------------------------------|---|--|
| <p>PIRFENIDONE</p> <p>Tablet 267 mg Tablet 801 mg</p> <p>Esbriet®</p> <p>Roche Products Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Idiopathic pulmonary fibrosis</p> | <p>To request an Authority Required listing for two new forms of pirfenidone.</p> | <p>The PBAC recommended the listing of pirfenidone as an Authority Required benefit for the treatment of idiopathic pulmonary fibrosis, as a 267 mg tablet and as a 801 mg tablet for continuing treatment only. The PBAC considered that the listing of the 801 mg tablet could potentially reduce the pill burden for some patients.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|---|--|---|
| <p>PNEUMOCOCCAL CONJUGATE VACCINE, 13 VALENT</p> <p>Injection 0.5 mL</p> <p>Prevenar 13®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>Prevention of pneumococcal disease</p> | <p>To request a change to the National Immunisation Program (NIP) infant schedule for 13-valent pneumococcal vaccine from a 3+0 to a 2+1 schedule.</p> | <p>The PBAC recommended that the circumstances of listing as designated vaccine for the purposes of the <i>National Health Act 1953</i> of 13-valent pneumococcal vaccine (13vPCV) for the prevention of pneumococcal disease should change such that:</p> <ul style="list-style-type: none"> • The general dosing schedule move from a ‘3+0’ to a ‘2+1’ schedule with doses provided to children at around 2 and 4 months of age with a booster in the second year of life. • For children in at risk conditions, the additional dose be provided at 6 months of age to adjust for the booster dose now to be given in the second year of life. • For Aboriginal and Torres Strait Islander children in at risk areas, the additional dose be provided at 6 months of age to adjust for the booster dose now to be given in the second year of life. • That the catch-up program allow for children who have received 3 previous doses of 13vPCV <12 months of age and present prior to 12 months of age to receive 1 further dose of 13vPCV in their second year of life with a minimum interval of 2 months after the previous dose of 13vPCV. <p>The PBAC accepted the advice of the Australian Technical Advisory Group on Immunisation (ATAGI) regarding the effectiveness of the change to the dosing schedule, noting that overall the proposed dosing schedule was of superior effectiveness and non-inferior in terms of comparative safety when compared to the existing dosing schedule.</p> <p>The PBAC considered that the change to dosing schedule of the 13vPCV was cost neutral, and may present a small cost saving, to the NIP as the number of doses provided would not change.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|---|--|--|
| <p>PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES</p> <p>Oral powder 450 g (Aptamil Gold+ Pepti-Junior)</p> <p>Aptamil Gold+ Pepti-Junior®</p> <p>Danone Nutricia</p> <p>Change to listing (Minor Submission)</p> | <p>Cow's milk protein enteropathy and intolerance to soy protein;</p> <p>Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein;</p> <p>Biliary atresia;</p> <p>Chronic liver failure with fat malabsorption;</p> <p>Chylous ascites;</p> <p>Cystic fibrosis;</p> <p>Enterokinase deficiency;</p> <p>Proven fat malabsorption;</p> <p>Severe diarrhoea of greater than 2 weeks duration;</p> <p>Severe intestinal malabsorption including short bowel syndrome</p> | <p>To request changes to the Authority Required (STREAMLINED) listing of Aptamil Gold+ Pepti-Junior including nutritional content.</p> | <p>The PBAC recommended the continued listing of protein hydrolysate formula with medium chain triglycerides (Aptamil Gold + Pepti-Junior) with the change in nutritional profile, including changes in fat, minerals and vitamins. The PBAC noted that the Nutritional Product Working Party supported this recommendation.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--|--|---|
| <p>RAMUCIRUMAB</p> <p>Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 500 mg in 50 mL</p> <p>Cyramza®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>New listing (Major Submission)</p> | <p>Advanced gastric or gastro-oesophageal junction adenocarcinomas</p> | <p>To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with advanced or metastatic, gastric or gastro-oesophageal junction adenocarcinoma in with disease progression, in combination with paclitaxel after prior platinum and fluoropyrimidine chemotherapy.</p> | <p>The PBAC recommended the Authority Required (STREAMLINED) listing of ramucirumab for the treatment of gastric or gastro-oesophageal junction (G/GEJ) adenocarcinoma. In making this recommendation, the PBAC noted that G/GEJ adenocarcinoma is a highly aggressive cancer with poor response to chemotherapy.</p> <p>The PBAC considered that while the submission's claim of superior comparative effectiveness over paclitaxel monotherapy was acceptable, the survival improvement in the RAINBOW trial was modest, the claim of non-inferior comparative safety was not reasonable, noting the significantly higher incidence of Grade 3 adverse events in the ramucirumab with paclitaxel arm, due to the cumulative effect of longer paclitaxel exposure and known anti-angiogenic effects of ramucirumab.</p> <p>The PBAC considered that the economic model presented an incremental cost-effectiveness ratio that was unacceptably high and optimistic, and included inappropriate assumptions about the rates of hospitalisations in the post-progression health state. As such, the PBAC recommended the PBS listing of ramucirumab with a substantial price reduction for it to be cost-effective in the proposed PBS population.</p> |
| <p>RANIBIZUMAB</p> <p>Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe Solution for intravitreal injection 2.3 mg in 0.23 mL</p> <p>Lucentis®</p> <p>Norartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p> | <p>Visual impairment due choroidal neovascularisation (CNV)</p> | <p>To request an Authority Required listing for the treatment of patients with rare choroidal neovascularisation CNV secondary to pathologic myopia.</p> | <p>The PBAC recommended extending the listing of ranibizumab as an Authority Required benefit to include treatment of subfoveal choroidal neovascularisation (CNV) secondary to pathologic myopia (PM). The PBAC considered that the nominated comparator of verteporfin photodynamic therapy was not appropriate to assess the cost-effectiveness of ranibizumab for this condition. However, on the basis of a modelled analysis of ranibizumab compared with sham injection (no treatment) with a wide range of scenario and sensitivity analyses, the PBAC considered that ranibizumab for the treatment of this condition was acceptably cost-effective.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--|--|---|
| <p>RANIBIZUMAB</p> <p>Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe</p> <p>Solution for intravitreal injection 2.3 mg in 0.23 mL</p> <p>Lucentis®</p> <p>Norvartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p> | <p>Visual impairment due to choroidal neovascularisation (CNV)</p> | <p>To request an Authority Required listing for the treatment of patients with visual impairment due to rare CNV.</p> | <p>The PBAC recommended extending the listing of ranibizumab as an Authority Required benefit to include treatment of subfoveal choroidal neovascularisation (CNV) due to rare causes. In making this recommendation, the PBAC considered that ranibizumab provides, for some patients, a significant improvement in efficacy compared with no active treatment. On the basis of a modelled analysis of ranibizumab compared with sham injection (no treatment) with a wide range of scenario and sensitivity analyses, the PBAC considered that ranibizumab for the treatment of this condition was acceptably cost-effective.</p> |
| <p>RANOLAZINE</p> <p>Tablet (modified release) 375 mg</p> <p>Tablet (modified release) 500 mg</p> <p>Tablet (modified release) 750 mg</p> <p>Ranexa®</p> <p>A. Menarini Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Stable angina pectoris</p> | <p>Resubmission to request an Authority Required listing as an add-on therapy for the symptomatic treatment of stable angina pectoris.</p> | <p>The PBAC recommended the Section 85 Authority Required (Telephone) listing of ranolazine. The Committee is satisfied that ranolazine provides, for some patients, a significant improvement in efficacy over placebo. The PBAC acknowledged the unmet clinical need in patients with stable angina whose symptoms are not controlled satisfactorily by the maximum tolerated doses of a beta-blocker or a calcium channel blocker, where revascularisation is not an option and haemodynamic concerns limit other anti-anginal treatment options. However, the PBAC was concerned that given the symptomatic nature of the condition and the broader TGA indication, that there was a high risk of leakage of using PBS-subsidised ranolazine outside of the PBS eligibility criteria. Therefore, the PBAC advised that a risk sharing arrangement was necessary to mitigate the financial risk to government.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|--|--|---|---|
| <p>RIBOCICLIB</p> <p>Tablet 200 mg</p> <p>Kisqali®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer</p> | <p>Resubmission to request an Authority Required listing as initial endocrine-based therapy in patients with HR+, HER2-locally advanced, inoperable or metastatic breast cancer in combination with a non-steroidal aromatase inhibitor, who are not premenopausal.</p> | <p>The PBAC recommended the listing of ribociclib in combination with a non-steroidal aromatase inhibitor (NSAI) (letrozole or anastrozole) as initial endocrine-based therapy in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced inoperable or metastatic breast cancer. The PBAC considered that for some patients, ribociclib in combination with an NSAI provides additional progression free survival, though its effect on overall survival is unknown. The PBAC noted that if overall survival was not improved by treatment with ribociclib then the observed gain in progression free survival would be at the expense of a reduced time spent in the post-progression state. The PBAC considered that the modelled cost-effectiveness was highly uncertain, but the Committee considered that the cost effectiveness of ribociclib could be brought into an acceptable range with a reduced effective price in conjunction with financial caps.</p> <p>The PBAC considered palbociclib an appropriate near market comparator. The PBAC noted that there are limited data to support the clinical claim for ribociclib compared with palbociclib but considered that the claim of non-inferior clinical effectiveness and safety appears reasonable.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|--|--|---|
| <p>RITUXIMAB</p> <p>Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL</p> <p>Riximyo®</p> <p>Sandoz Pty Ltd</p> <p>New listing (Minor Submission)</p> | <p>CD20 positive follicular B-cell non-Hodgkin's lymphoma; CD20 positive non-Hodgkin's lymphoma; Low-grade B-cell non-Hodgkin's lymphoma; Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)(GPA); Microscopic polyangiitis (MPA); Chronic lymphocytic leukaemia; Severe active rheumatoid arthritis (RA).</p> | <p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) and Section 100 Authority Required (Highly Specialised Drug) listings for the same indications as the reference biologic.</p> | <p>The PBAC recommended the listing of a biosimilar brand of rituximab (Riximyo®) for the same oncology and autoimmune indications as the IV infusion reference brand of rituximab (MabThera®), under the S100 Efficient Funding of Chemotherapy and Highly Specialised Drug programs. The PBAC recommended that the Riximyo and Mabthera brands of rituximab could be marked as equivalent ('a' flagged) in the Schedule of Pharmaceutical Benefits.</p> <p>The PBAC advised that there are no clinical or other concerns about appropriate use of medicines, if the policy decision were made to apply the biosimilar uptake measures agreed as part of the strategic agreement with Medicines Australia to rituximab, provided certain recommendations are followed:</p> <ul style="list-style-type: none"> • The PBAC deemed it reasonable to lower the authority level of the GPA/MPA and RA indications from a written authority to Authority Required (STREAMLINED) at the re-induction phase for GPA/MPA and at the subsequent continuing phase for RA. • The PBAC advised against lowering the benefit level of the oncology indications from a Streamlined Authority to a Restricted Benefit, as it is expected that this would have minimal effect on prescribing behaviours and may inadvertently lead to an increase in prescribing beyond the current restrictions. <p>The PBAC recommended the addition of a note encouraging prescribing of the biosimilar brand to treatment naïve patients, would be appropriate for all indications.</p> |

MARCH 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

| DRUG, SPONSOR, TYPE OF SUBMISSION | DRUG TYPE OR USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME |
|---|---|---|--|
| <p>TRIGLYCERIDES, LONG CHAIN WITH GLUCOSE POLYMER</p> <p>Oral liquid 250 mL, 18 Oral liquid 1 L, 6</p> <p>ProZero®</p> <p>Vitaflo Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p> | <p>Proven inborn errors of protein metabolism</p> | <p>To request changes to the Restricted Benefit listing of ProZero including nutritional content.</p> | <p>The PBAC noted the change to the formulation processed by the Secretariat and noted the listing of ProZero would not be altered by this change.</p> |