

NOVEMBER 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>AMINO ACIDS-SYNTHETIC, FORMULA</p> <p>Oral powder 400 g (Neocate Junior Vanilla)</p> <p>Neocate Junior® Vanilla</p> <p>Nutricia Australia Pty Limited</p> <p>Change to listing (Minor Submission)</p>	<p>Cow's milk allergy, multiple protein food intolerance and other medical conditions where an elemental diet is required</p>	<p>To request a formulation change to the existing Authority Required listing of Neocate Junior Vanilla.</p>	<p>The PBAC agreed with the change to the formulation processed by the Secretariat and specifically noted the change in scoop size and sponsor's intention to notify all relevant healthcare professionals and consumers of this change to ensure patients continue to receive appropriate dosing.</p>
<p>BRENTUXIMAB VEDOTIN</p> <p>Powder for I.V. infusion 50 mg</p> <p>Adcetris®</p> <p>Takeda Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Cutaneous T-cell lymphomas (CTCL)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of refractory or relapsed CD30 positive cutaneous T-cell lymphomas (CTCL).</p>	<p>The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required listing of brentuximab vedotin for the treatment of refractory or relapsed (RR) CD30 positive cutaneous T-cell lymphomas (CTCL). The PBAC recognised the clinical need for effective treatments in this population and was satisfied that brentuximab vedotin provides, for some patients with the mycosis fungoides (MF), sézary syndrome (SS) and primary cutaneous anaplastic large cell lymphoma (pcALCL) subtypes of CTCL, a significant improvement in efficacy over methotrexate. The PBAC noted that the lymphomatoid papulosis CTCL subtype is not consistently defined as a cancer and most patients do not require treatment with brentuximab vedotin, and recommended that this subtype be excluded from the listing. The PBAC considered that brentuximab vedotin was cost-effective compared with methotrexate for the MF, SS and pcALCL CTCL subtypes at the revised price proposed in the minor resubmission.</p>

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<p>ENCORAFENIB and BINIMETINIB</p> <p>Encorafenib: capsule 50 mg capsule 75 mg</p> <p>Binimetinib: tablet 15 mg</p> <p>BRAFTOVI® and MEKTOVI®</p> <p>Pierre Fabre Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Melanoma</p>	<p>To request an Authority Required (STREAMLINED) listing for the concurrent use of encorafenib and binimetinib for the treatment of BRAFV600 mutation positive unresectable Stage III or metastatic (Stage IV) melanoma.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of encorafenib in combination with binimetinib, for the treatment of BRAF V600 mutation positive unresectable Stage III or Stage IV metastatic melanoma, on a cost-minimisation basis against dabrafenib+trametinib and vemurafenib+cobimetinib. The equi-effective doses were encorafenib 450 mg once daily + binimetinib 45 mg twice daily or dabrafenib 150 mg twice daily + trametinib 2 mg once daily or vemurafenib 960 mg twice daily + cobimetinib 60 mg once daily (21 days on treatment plus 7 days off-treatment, in a 28-day cycle).</p>
<p>FERRIC CARBOXYMALTOSE</p> <p>Injection 1,000 mg (iron) in 20 mL</p> <p>Ferinject®</p> <p>Vifor Pharma Pty Limited</p> <p>New listing (Minor Submission)</p>	<p>Iron deficiency anaemia</p>	<p>To request an unrestricted benefit listing for a new strength of iron injection.</p>	<p>The PBAC recommended the listing of ferric carboxymaltose 1,000 mg/20 mL in addition to the existing 500 mg/10 mL presentation, on the General Schedule as an unrestricted benefit for the treatment of iron deficiency anaemia (IDA).</p>

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<p>FOLLITROPIN ALFA with LUTROPIN ALFA</p> <p>Injection 900 I.U. - 450 I.U. in 1.44 mL multi-dose cartridge</p> <p>Pergoveris®</p> <p>Merck Serono Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Stimulation of follicular development</p>	<p>To request a Section 100 (IVF program) listing of a new form of follitropin alfa with lutropin alfa.</p>	<p>The PBAC recommended the Section 100 (IVF program) Authority Required (STREAMLINED) listing of a new form of follitropin alfa with lutropin alfa (Pergoveris®) for stimulation of follicular development, at the same price per dose as the currently listed formulation.</p>
<p>GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS</p> <p>Oral liquid 250 mL, 30 (PKU Glytactin RTD 15 Lite)</p> <p>PKU Glytactin RTD 15 LITE</p> <p>Cortex Health Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Phenylketonuria (PKU)</p>	<p>To request a Restrict Benefit listing for the treatment of PKU.</p>	<p>The PBAC recommended the Restricted Benefit listing of a new form of glycomacropeptide and essential amino acids with vitamins and minerals (PKU Glytactin RTD 15 Lite®) on a cost-minimisation basis to the comparator PKU Glytactin RTD 15® for the treatment of phenylketonuria (PKU) at an equivalent cost per gram of protein equivalent (PE).</p>

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<p>GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE</p> <p>Sachets containing oral powder 33.3 g, 16 (PKU GMPPro)</p> <p>PKU GMPPro</p> <p>Nutricia Australia Pty Limited</p> <p>New listing (Minor Submission)</p>	<p>Phenylketonuria (PKU)</p>	<p>To request a Restrict Benefit listing for the treatment of PKU.</p>	<p>The PBAC recommended the request of a Restricted Benefit listing of a new form of glycomacropeptide formula with docosahexaenoic acid with low phenylalanine (PKU GMPPro®) on a cost-minimisation basis to the nominated comparator PKU Glytactin RTD 10 for the treatment of phenylketonuria (PKU) at an equivalent cost per gram of protein equivalent (PE).</p> <p>The PBAC considered that the Maximum Quantity should be 8 instead of 14 as proposed by the submission.</p>
<p>HYPROMELLOSE</p> <p>Eye drops 3 mg per mL, 10 mL</p> <p>In a Wink Moisturising®, Genteal®</p> <p>Alcon Laboratories (Australia) Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Severe dry eye syndrome, including Sjogren's syndrome</p>	<p>To request a change in pack size for the In a Wink Moisturising® and Genteal® brands of hypromellose.</p>	<p>The PBAC agreed with the change to the pack size to a smaller 10mL bottle processed by the Secretariat.</p>

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<p>INACTIVATED QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION)</p> <p>Injection 0.5mL in pre-filled syringe</p> <p>Afluria® Quad</p> <p>Seqirus Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Prevention of seasonal influenza</p>	<p>To extend the current National Immunisation Program (NIP) listing to include persons aged 5-17 years who are currently eligible for vaccination through the NIP with other brands of influenza vaccine.</p>	<p>The PBAC recommended the expansion of the population in which inactivated quadrivalent influenza vaccine (QIV), Afluria® Quad, may be available on the National Immunisation Program (NIP) for the prevention of influenza to include persons aged 5 to 17 years (inclusive) who are currently eligible for other brands of QIV through the NIP; specifically:</p> <ul style="list-style-type: none"> • People aged 5 to 17 years with increased risk of complications from influenza, as defined in subsection 7(8)A(c) of the Determination; • Women who are pregnant; and • Aboriginal and/or Torres Strait Islander people aged 15 to 17 years. <p>At the same meeting, the PBAC recommended that two brands of QIV currently listed on the NIP may be provided to Aboriginal and/or Torres Strait Islander people aged 5 to 14 years. Accordingly, in addition to the above recommendation, the PBAC recommended that Afluria Quad may also be available through the NIP for Aboriginal and/or Torres Strait Islanders aged 5 to 14 years.</p> <p>The PBAC's recommendation was made on a cost-minimisation basis to comparators Fluarix Tetra® and FluQuadri™ using the equi-effective doses of one dose of FluQuadri 0.5mL or Fluarix Tetra 0.5mL to a 0.5mL dose of Afluria Quad.</p>
<p>INOTUZUMAB OZOGAMICIN</p> <p>Powder for I.V. infusion 1 mg</p> <p>Besponsa®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Acute lymphoblastic leukaemia (ALL)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of relapsed or refractory CD22 positive B-cell precursor acute lymphoblastic leukaemia (ALL).</p>	<p>The PBAC recommended the Authority Required listing of inotuzumab for the treatment of relapsed or refractory Philadelphia chromosome negative B-precursor acute lymphocytic leukaemia, on the basis that it should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy). The PBAC recommended the listing on a cost-minimisation basis against blinatumomab.</p> <p>The PBAC considered that sequential use of inotuzumab and blinatumomab (in either order) would be clinically appropriate in some patients given the differing mechanisms of action and the clinical role for additional therapeutic options for patients who are unable to receive a haematopoietic stem cell transplant (HSCT) or who progress after a HSCT.</p>

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<p>INSULIN ASPART</p> <p>Injections (human analogue), pre filled pen, 100 units per mL, 3mL Injections (human analogue), vial, 100 units per mL, 10 mL Injections (human analogue), cartridges, 100 units per mL, 3 mL</p> <p>Fiasp®</p> <p>Novo Nordisk Pharmaceuticals Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Diabetes Mellitus</p>	<p>To request an unrestricted benefit listing for diabetes mellitus.</p>	<p>The PBAC recommended the listing of a new form of insulin aspart (Fiasp®) for the treatment of diabetes mellitus in adults on the basis of non-inferiority to the comparator NovoRapid®. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Fiasp would be acceptable if it were cost-minimised against NovoRapid on a unit for unit basis.</p>
<p>ISOTRETINOIN</p> <p>Capsule 5 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 strength of isotretinoin for the treatment of severe cystic acne.</p>	<p>The PBAC recommended the listing of the new strength of isotretinoin for the treatment of severe cystic acne. The PBAC accepted that the additional strength would provide a therapeutic alternative for patients who require a lower dose of isotretinoin.</p>

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<p>LACOSAMIDE</p> <p>Tablet 50 mg Tablet 100 mg Tablet 150 mg Tablet 200 mg Oral liquid 10 mg per mL, 200 mL</p> <p>Vimpat®</p> <p>UCB Pharmaceuticals Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Partial epileptic seizures</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of intractable partial epileptic seizures for patients aged 4 to 15 years.</p>	<p>The PBAC recommended an extension to the existing Authority Required (Streamlined) listing for lacosamide, and a new listing for lacosamide oral liquid, for treatment of intractable partial epileptic seizures in combination with two or more anti-epileptic drugs (AEDs), to include patients aged 4 – 15 years.</p> <p>The PBAC were satisfied that lacosamide provides, for some patients, a significant reduction in seizure frequency over placebo. The PBAC accepted the clinical place for the proposed therapy and noted that there is a high unmet clinical need for additional treatment options in this highly refractory population where seizures have not been satisfactorily controlled by other antiepileptic drugs.</p>
<p>LENVATINIB</p> <p>Capsule 4 mg (as mesilate)</p> <p>Lenvima®</p> <p>Eisai Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Hepatocellular carcinoma</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable hepatocellular carcinoma.</p>	<p>The PBAC reaffirmed its July 2018 advice that lenvatinib be listed on a cost-minimisation basis compared to sorafenib with the equi-effective doses based on the mean treatment durations and mean doses from a head-to-head trial comparing lenvatinib to sorafenib. The PBAC recommended that it may be reasonable that the drug cost for lenvatinib be no more than 5% higher than the price of sorafenib using the previously recommended equi-effective doses, reflecting its different safety profile. In particular, the PBAC noted the rate of palmar-plantar erythrodysesthesia syndrome was lower with lenvatinib (26.9%, all grades; 2.9% Grade ≥3) compared to sorafenib (52.4%, all grades; 11.4%, Grade ≥3) and this adverse event may have a significant impact on a patient's quality of life.</p>

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<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</p> <p>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® and Yervoy®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Renal cell carcinoma (RCC)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the concurrent use of nivolumab and ipilimumab for the treatment of Stage IV clear cell variant renal cell carcinoma (RCC)</p>	<p>The PBAC recommended the Section 100 (Efficient funding of chemotherapy) Authority Required (STREAMLINED) listing of nivolumab in combination with ipilimumab (NIVO+IPI) for the first-line treatment of Stage IV clear cell variant renal cell carcinoma (RCC) in patients at intermediate to poor prognostic risk.</p> <p>In making this recommendation, the PBAC acknowledged that there is a high clinical need for effective first-line therapies for RCC, especially in the poor-risk patient population for whom no PBS-subsidised therapies are currently available.</p> <p>The PBAC considered that the resubmission's revised economic model parameters, utilisation estimates and risk-sharing arrangement helped to address many of its previous concerns. However, the PBAC advised that the price of NIVO+IPI needed to be reduced to bring the estimated incremental cost-effectiveness ratio into an acceptable range.</p>
<p>OSIMERTINIB</p> <p>Tablet 40 mg Tablet 80 mg</p> <p>Tagrisso®</p> <p>Astra Zeneca Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>Resubmission to request an Authority Required listing for the treatment of patients with locally advanced or metastatic epidermal growth factor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC) who have progressed on or after prior treatment with an EGFR tyrosine kinase inhibitor (TKI).</p>	<p>The PBAC recommended the Section 85 Authority Required (written) listing of osimertinib for the treatment of EGFR T790M mutation positive NSCLC. The PBAC acknowledged that osimertinib provides, for some patients, a significant improvement in efficacy and a reduction in toxicity over platinum-based doublet chemotherapy. The PBAC noted there is an unmet clinical need for treatment options as patients with EGFR mutation positive NSCLC develop acquired resistance to first-line EGFR TKI therapy. The PBAC considered the proposed RSA adequately addressed its previous concerns regarding the utilisation and cost-effectiveness of osimertinib.</p>

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<p>PEGFILGRASTIM</p> <p>Injection 6 mg in 0.6 mL single use pre-filled syringe</p> <p>Fulphila®</p> <p>Alphapharm Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Chemotherapy-induced neutropenia</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required (STREAMLINED) listing of this biosimilar brand for all indications for which the reference biologic is currently PBS listed.</p>	<p>The PBAC recommended the listing of the biosimilar brand of pegfilgrastim, Fulphila®, on the Section 100 Highly Specialised Drugs (HSD) program, for all indications for which the pegfilgrastim reference brand (Neulasta®) is currently PBS listed.</p> <p>The PBAC advised that the Fulphila®, Neulasta® and Ristempa® brands of pegfilgrastim should be considered equivalent for the purpose of substitution (i.e., 'a' flagged).</p> <p>The PBAC advised that there were no clinical or other concerns about appropriate use of medicines, if the policy decision were made to apply the following biosimilar uptake drivers to the requested listing:</p> <ul style="list-style-type: none"> • encouraging the prescribing of biosimilar pegfilgrastim for treatment naïve patients by the addition of a note in the schedule; and • in principle, applying a lower level of authority to biosimilar pegfilgrastim than exists for the reference brand. The PBAC noted that applying a lower level of authority for the Fulphila® brand cannot be implemented at this time, as listings in Section 100 must be either Authority Required or streamlined authority items (i.e. cannot be a Restricted Benefit or unrestricted listings), and pegfilgrastim is already a streamlined authority listing.

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Melanoma</p>	<p>To request removal of the weight-based dosing option for pembrolizumab in unresectable stage III or Stage IV malignant melanoma.</p>	<p>The PBAC noted the impending change to the dose regimens in the Product Information to remove the weight-based dosing option (leaving fixed dosing) and agreed for changes to the listing to be processed by the Secretariat following finalisation of the associated TGA matters in relation to this change.</p> <p>The PBAC recalled its March 2018 recommendation to amend the PBS restrictions for pembrolizumab for this indication to allow either a weight-based dose of 2 mg/kg or a fixed dose of 200 mg, every three weeks and that it had concluded at that time that the 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. The PBAC reiterated its earlier advice that while the current annual expenditure cap arrangements limited any increase in expenditure to Government, future deeds of agreement would need to include a price reduction to ensure no net effect on the per-patient costs of pembrolizumab to ensure that the PBS listing remains acceptably cost-effective.</p>
<p>PONATINIB</p> <p>Tablet 15 mg (as hydrochloride) Tablet 45 mg (as hydrochloride)</p> <p>Iclusig®</p> <p>Specialised Therapeutics Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chronic myeloid leukaemia (CML)</p>	<p>To request amendments to the circumstances under which ponatinib is subsidised for the treatment of CML.</p>	<p>The PBAC recommended an amendment to the Authority Required (Written) listing for ponatinib for the treatment of chronic myeloid leukaemia (CML), to enable telephone authority for subsequent continuing treatment. The PBAC also recommended an amendment to remove reference to the six month timeframe between bone marrow biopsy pathology report(s) and the application for initiation of treatment.</p>

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<p>RILUZOLE</p> <p>Oral liquid 50 mg per 10 mL, 300 mL</p> <p>Teglutik®</p> <p>Seqirus (Australia) Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Amyotrophic lateral sclerosis (ALS)</p>	<p>To request an Authority Required listing of an oral liquid form of riluzole for the treatment of ALS.</p>	<p>The PBAC recommended the General Schedule, Authority Required listing of a new liquid formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS). The PBAC considered the liquid form would have advantages for patients who may have difficulty taking tablets, such as those with swallowing difficulties or who use a percutaneous endoscopic gastrostomy.</p>
<p>RIVAROXABAN</p> <p>Tablet 10 mg</p> <p>Xarelto®</p> <p>Bayer Australia Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Venous thromboembolism</p>	<p>To request an Authority Required (STREAMLINED) listing for the prevention of recurrent venous thromboembolism.</p>	<p>The PBAC recommended the listing of rivaroxaban 10 mg for the prevention of recurrent venous thromboembolism (VTE) on a cost-minimisation basis with rivaroxaban 20 mg once daily and apixaban 2.5 mg twice daily. The PBAC noted that this offers a lower strength alternative for patients who require ongoing treatment.</p>
<p>SAFINAMIDE</p> <p>Tablet 50 mg Tablet 100 mg</p> <p>Xadago®</p> <p>Seqirus Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Parkinson disease</p>	<p>To request a Restricted Benefit listing for the treatment of patients with Parkinson disease, as add-on therapy to a regimen that includes levodopa, in patients experiencing motor fluctuations.</p>	<p>The PBAC recommended the listing of safinamide as a Restricted Benefit listing for treatment of Parkinson's disease, as add-on therapy to levodopa, on the basis of cost-minimisation compared to rasagiline. The equi-effective doses are safinamide 100 mg/day and rasagiline 1 mg/day.</p>

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<p>SAPROPTERIN</p> <p>Tablet (soluble) containing sapropterin dihydrochloride 100 mg</p> <p>Kuvan®</p> <p>BioMarin Pharmaceutical Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Hyperphenylalaninemia (HPA)</p>	<p>Resubmission to request an Authority Required listing for the treatment of HPA in patients with phenylketonuria.</p>	<p>The PBAC recommended the PBS-listing of sapropterin for the treatment of hyperphenylalaninaemia (HPA) caused by phenylketonuria (PKU) as a Section 85 Authority Required listing. The PBAC was satisfied that sapropterin provides, for some patients, a significant improvement in efficacy over a phenylalanine-restricted diet alone. In making this recommendation, the PBAC noted there was a high clinical need in a small patient population, and acknowledged the input received from individuals, organisations and health professionals. The PBAC considered that a risk sharing arrangement (RSA) would be required to manage the high and uncertain cost-effectiveness, the uncertain patient population, and the risk of use in patients not continuing to respond.</p> <p>The PBAC considered that the greatest clinical benefits would be achieved in children and adolescents and considered that sapropterin should only be commenced in patients who are younger than 18 years of age. The PBAC considered that patients who commenced PBS-subsidised sapropterin prior to the age of 18 years should be allowed to continue sapropterin thereafter. This was in light of the risks of ceasing treatment once commenced and the sponsor's RSA proposal which would help address the cost-effectiveness and financial impacts for continuing patients.</p>

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<p>SARILUMAB</p> <p>Injection 200 mg in 1.14 mL pre-filled syringe Injection 150 mg in 1.14 mL pre-filled syringe</p> <p>Kevzara®</p> <p>Sanofi-Aventis Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Rheumatoid arthritis</p>	<p>To request an Authority Required listing for the treatment of patients with severe active rheumatoid arthritis.</p>	<p>The PBAC recommended the authority required listing of sarilumab on a cost minimisation basis with the least costly biological disease modifying anti-rheumatic drug (bDMARD) for severe active rheumatoid arthritis (RA). The PBAC considered sarilumab 200mg once every two weeks was non-inferior to tocilizumab 162mg given subcutaneously every week and sarilumab 150mg once every two weeks was non-inferior to a reduced dose regimen of tocilizumab 162mg subcutaneously given once every two weeks to patients who experienced adverse events necessitating a reduction in dose.</p> <p>The PBAC noted it had previously considered tocilizumab to be of non-inferior comparative safety and efficacy to other alternative bDMARDs PBS listed for RA and therefore considered sarilumab was also likely to be non-inferior to these alternatives. For the 150mg strength, the PBAC considered pricing consistent with the cost of a reduced-frequency dose regimen of subcutaneous tocilizumab 162mg once every two weeks was appropriate and that continuation on the 150mg strength was a matter of clinical judgment.</p>
<p>SEASONAL INFLUENZA VACCINES</p> <p>Injection 0.5 mL in pre-filled syringe</p> <p>Afluria® Quad FluQuadri® Fluarix Tetra®</p> <p>Seqirus (Australia) Pty Ltd Sanofi-Aventis Australia Pty Ltd GlaxoSmithKline Australia Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Prevention of seasonal influenza</p>	<p>To request listing of seasonal influenza vaccines on the National Immunisation Program (NIP) for Aboriginal and Torres Strait Islander children and adolescents aged 5 - 14 years.</p>	<p>The PBAC recommended that two brands of quadrivalent influenza vaccines, FluQuadri and Fluarix Tetra, may be provided on the NIP for the prevention of influenza in Aboriginal and/or Torres Strait Islander (Indigenous) persons aged 5 to 14 years. The PBAC noted that the NIP currently provides free seasonal influenza vaccine each year to Indigenous people aged 6 months to 4 years and 15 years and older. The recommended change would provide access to seasonal influenza vaccine to all Indigenous people aged 6 months and older at no cost through the NIP.</p> <p>At the same meeting, the PBAC recommended a change to the circumstances for Afluria Quad to allow use in people aged 5 years and older who are already eligible for other brands of influenza vaccine through the NIP. The PBAC considered that the recommendation for changes for Afluria Quad should also include Aboriginal and Torres Strait Islander people aged 5 to 14 years.</p>

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<p>TESTOSTERONE</p> <p>Transdermal gel (pump pack) 23 mg per 1.15 g dose, 56 doses</p> <p>Testavan®</p> <p>Ferring Pharmaceuticals Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Androgen deficiency; Micropenis; Pubertal induction; Constitutional delay of growth or puberty</p>	<p>To request an Authority Required listing for the treatment of male hypogonadism.</p>	<p>The PBAC recommended the listing of testosterone 2% enhanced permeation (EP) gel for the treatment of androgen deficiency. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost effectiveness of testosterone 2% EP gel would be acceptable if it were cost-minimised against the currently listed testosterone 1% gel. The equi-effective doses were 60.07 mg testosterone of 2% EP gel and 75.78 mg testosterone of 1% gel.</p>
<p>TIOTROPIUM</p> <p>Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)</p> <p>Spiriva® Respimat®</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Asthma</p>	<p>Resubmission to extend the current Authority Required (STREAMLINED) listing to include treatment of severe asthma for children and adolescents aged 6 to 17 years.</p>	<p>The PBAC recommended the Authority Required (STREAMLINED) listing of tiotropium for the treatment of severe asthma in children and adolescents aged 6-17 years who have not achieved adequate asthma control with optimised asthma therapy. The PBAC considered that the similar magnitude of benefit observed across trial populations (6-11 years, 12-17 years, and ≥ 18 years), supported the premise that age is not a treatment effect modifier for tiotropium in severe asthma. As such, the PBAC considered that the comparative benefit of add-on tiotropium over placebo in children and adolescents aged (6-17 years) with severe asthma was adequately supported by the evidence provided in the resubmission and that as the magnitude of benefit was similar between populations, it was reasonable to accept the cost-effectiveness of tiotropium in the child and adolescent population at the same price as in the adult population.</p>
<p>TOFACITINIB</p> <p>Tablet 5 mg</p> <p>Xeljanz®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Psoriatic arthritis</p>	<p>To request an Authority Required listing for the treatment of patients with severe active psoriatic arthritis who have had an inadequate response to methotrexate and disease modifying anti-rheumatic drugs.</p>	<p>The PBAC recommended the Authority Required listing of tofacitinib on a cost minimisation basis with the least costly biological disease modifying anti-rheumatic drug (bDMARD) for psoriatic arthritis (PsA).</p>

NOVEMBER 2018 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>VENETOCLAX</p> <p>Tablet 10 mg Tablet 50 mg Tablet 100 mg</p> <p>Venclexta®</p> <p>AbbVie Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Relapsed or refractory chronic lymphocytic leukaemia</p>	<p>To request an Authority Required listing, in combination with rituximab, for the treatment of patients with relapsed or refractory CLL who are unsuitable for treatment with a purine analogue.</p>	<p>The PBAC recommended the listing of venetoclax in combination with rituximab for the treatment of certain patients with relapsed or refractory chronic lymphocytic leukaemia. The PBAC recommended listing on a cost-minimisation basis compared to ibrutinib. The PBAC advised sequential use of venetoclax plus rituximab and ibrutinib was likely to occur and may be clinically appropriate given the different mechanism of action and the emerging evidence. However, the PBAC considered the cost-effectiveness of this sequential use was uncertain and its financial implications could be high and also highly uncertain. Therefore, the PBAC recommended venetoclax be listed with the same restriction criteria as ibrutinib and that the requested listing of venetoclax and rituximab be included in the current risk sharing arrangement for ibrutinib with no change to the annual expenditure caps.</p>