NOVEMBER 2020 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
DUPILUMAB Injection 200 mg in 1.14 mL single use prefilled syringe; Injection 300 mg in 2 mL single use pre-filled syringe Dupixent® Sanofi-Aventis Australia Pty Ltd New listing (Other)	Atopic dermatitis	To request that the PBAC review a revised proposal following the March 2020 recommendation for dupliumab for the treatment of patients with chronic severe atopic dermatitis who have had an inadequate response to topical therapies.	The PBAC provided further advice in regard to its March 2020 recommendation for the listing of dupilumab, for the treatment of patients aged 12 years and older with severe atopic dermatitis who are inadequately controlled on topical therapies, and the sponsor's subsequent listing proposal which included modifications to the economic model and the financial estimates model. Overall, the PBAC considered that the modifications the sponsor made to the economic model were still potentially based on optimistic assumptions that favoured dupilumab, however considered them to be acceptable in the context of high clinical need in this therapeutic area, along with a corresponding price reduction to achieve the same base case incremental cost effectiveness ratios (ICERs) reviewed in March 2020. In relation to the utilisation estimates, the PBAC noted that the sponsor's proposal resulted in a significant increase to the total cost associated with the listing of dupilumab, and considered that the cost of the listing should be more closely aligned with the estimates based on the PBAC's March 2020 recommended approach.
GALCANEZUMAB Injection 120 mg in 1 mL pre-filled pen Emgality® Eli Lilly Australia Pty Ltd New listing (Minor Submission)	Chronic migraine	Resubmission to request an Authority Required (STREAMLINED) listing for the prophylactic treatment of patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications.	The PBAC provided further advice in regard to its July 2019 recommendation for the listing of galcanezumab for the treatment of chronic migraine. The PBAC considered galcanezumab was cost effective if cost-minimised to Botox. The PBAC considered a separate risk sharing arrangement for galcanezumab was reasonable, however advised revisions to the financial estimates, expenditure caps and rebate levels would be required to ensure cost-effective use.

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TOFACITINIB Tablet 5 mg Tablet 10 mg Xeljanz® Pfizer Australia Pty Ltd Change to recommended listing (Minor Submission)	Chronic plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ulcerative colitis"	To request that the PBAC review its advice on the interchangeability of tofacitinib on an individual patient basis with other biological disease modifying antirheumatic drugs under Section 101(3BA) of the *National Health Act 1953*.	The PBAC replaced its previous advice to the Minister under Section 101(3B) of the *National Health Act 1953*. This revised advice was reached, in part, on the basis that, to date none of the drugs in each of the below groups has been demonstrated to provide better health outcomes than any other and are therefore considered to provide similar outcomes in terms of effectiveness and safety. The PBAC replaced its previous advices with the following: For moderate to severe ulcerative colitis, the drugs infliximab, vedolizumab and tofacitinib should be treated as interchangeable on an individual patient basis. For psoriatic arthritis, the drugs etanercept, adalimumab, infliximab, ixekizumab and golimumab should be treated as interchangeable on an individual patient basis. In addition, for psoriatic arthritis, the drugs certolizumab pegol, guselkinumab, ustekinumab, secukinumab and tofacitinib should be treated as interchangeable on an individual patient basis. The PBAC clarified that its most recent advices on the “biologics” that should be treated as interchangeable on an individual patient basis for severe active rheumatoid arthritis (November 2019) and for severe chronic plaque psoriasis (July 2019) represented its current views (and had been intended to supersede earlier views that it had expressed on the same topics). Further information on the reasons for PBAC’s advice will be contained in the Public Summary Document for this item.

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UPADACITINIB Tablet 15 mg Rinvoq® Abbvie Pty Ltd Change to listing (Minor Submission)	Severe rheumatoid arthritis (RA)	Resubmission to request review of the statistical basis upon which the claim of superior effectiveness versus adalimumab for the treatment of patients with severe active RA was not accepted.	The PBAC reaffirmed its view that overall upadacitinib (UPA), baricitinib and adalimumab (ADA) are non-inferior in terms of effectiveness when used for the treatment of severe active RA. The PBAC acknowledged that results from the SELECT-COMPARE trial demonstrated a statistically significant improvement of UPA over ADA. However, the PBAC considered that the available evidence did not adequately support there being a clinically relevant difference in effectiveness between UPA and ADA. The PBAC requested a corrigenda to the November 2019 UPA Public Summary Document be issued.

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Review of PBS Authority Required (Written) listings- Tranche 1	Medicines for the treatment of blood cancers and glioblastoma	To request that the Pharmaceutical Benefit Advisory Committee (PBAC) consider the Authority Required (Written) restriction level for PBS-listed medicines (tranche 1) and recommend any required amendments.	The PBAC noted the key Review findings from the PBS Authority Required (Written) listings report, which included an analysis of PBS utilisation data for Tranche 1 medicines. The PBAC also noted the input provided by sponsors through submission of pre-subcommittee responses (PSCRs) on the written authority level of their Tranche 1 medicine(s). The PBAC applied the following key criteria to assist in determining the requirement to maintain a written Authority level of restriction: (1) Potential for use in a population in which the medicine is not cost-effective or where the PBAC has not determined the comparative effectiveness and cost; and (2) Potential for high cost per patient or high total cost to the health system and the government's budget. The PBAC also considered the following factors: quality use of medicines (QUM), safety, and administrative burden. Overall, the PBAC accepted the DUSC October 2020 advice on the need to amend or maintain the current written Authority level of each medicine and made the following recommendations:
blinatumomab, dasatinib, inotuzumab ozogamicin, ponatinib	Acute lymphoblastic leukaemia		**Acute lymphoblastic leukaemia:** The PBAC did not recommend amendments to the PBS restrictions for dasatinib due to its place as second-line therapy and potential risk of leakage to other indications. The PBAC did not recommend changes to the PBS restriction level for ponatinib, due to the risk of potential of leakage to other indications. The PBAC did not recommend an amendment to the PBS restriction level for blinatumomab and inotuzumab ozogamicin due to the high PBS expenditure associated with salvage therapy, the relatively low administrative burden and large financial risk to the government.
midostaurin, azacitidine	Acute myeloid leukaemia		**Acute myeloid leukaemia:** The PBAC did not recommended an amendment to the PBS restriction level for midostaurin, as the market has not yet stabilised, there is potential for unintended use in other indications (leakage) and the associated financial implications to government.

			The PBAC recommended the PBS restriction level for azacitidine to be decreased to Authority Required (Telephone) for initial treatment and Authority Required (STREAMLINED) for continuing treatment. The PBAC recommended that DUSC review the utilisation of azacitidine in AML, MDS and CMML to capture potential leakage into other indications.
idelalisib	Chronic lymphocytic leukaemia and small lymphocytic lymphoma		**Chronic lymphocytic leukaemia and small lymphocytic lymphoma:** The PBAC noted that ibrutinib and venetoclax were omitted from the review, and therefore agreed to include idelasilib in its consideration of all CLL and SLL medicines in Tranche 2.
dasatinib, nilotinib, ponatinib	Chronic myeloid leukaemia		**Chronic myeloid leukaemia:** The PBAC did not recommend an amendment to the PBS restriction level for ponatinib due to the high risk of leakage into other indications and different toxicity profile to second-line treatments (dasatinib and nilotinib). The PBAC recommended decreasing the PBS restriction level for nilotinib and dasatinib to Authority Required (Telephone) for initial treatment, and Authority Required (STREAMLINED) for first and subsequent continuing treatment. The PBAC recommended that DUSC review the utilisation of dasatinib and nilotinib in 12 months.
lenalidomide, pomalidomide	Multiple myeloma		**Multiple myeloma:** The PBAC did not recommend amendments to the PBS restriction level for lenalidomide, due to high PBS expenditure, a market that is not yet stable and potential leakage to other indications. The PBAC did not recommend amendments to the PBS restrictions for pomalidomide. The PBAC agreed that as pomalidomide is reserved for second-line therapy in MM, easing restrictions could increase risk of leakage into first-line use.
brentuximab vedotin	Systemic anaplastic large cell lymphoma		**Systemic anaplastic large cell lymphoma:** The PBAC did not recommend amendments to the PBS restriction level for brentuximab vedotin, due to potential leakage to other indications.
idelalisib	Refractory follicular B-cell non-Hodgkin's lymphoma		**Refractory follicular B-cell non-Hodgkin’s lymphoma:** The PBAC recommended an amendment to the PBS restriction level for idelalisib to Authority Required (Telephone) for the initial treatment phase,

			and Authority Required (STREAMLINED) for the continuing treatment phase. The PBAC also recommended that DUSC review the utilisation of idelalisib for this indication in 12 months' time due to safety concerns.
brentuximab vedotin, pembrolizumab	Hodgkin's lymphoma		**Hodgkin's lymphoma** The PBAC considered that stabilisation of the market is required before changes to written authority restrictions for brentuximab vedotin and pembrolizumab may be considered. The PBAC considered that lowering the restriction level to access initial treatment, to Authority Required (STREAMLINED), would increase the risk of potential leakage of both medicines to other lymphoma indications.
bevacizumab ALL FORMS,STRENGTHS and LISTED BRANDSRANDS	Glioblastoma		**Glioblastoma** The PBAC did not recommend amendments to the PBS restriction level for glioblastoma. The PBAC noted that bevacizumab for glioblastoma was PBS listed on 1 August 2019 and that the market has yet to stabilise. The PBAC considered that the cost-effectiveness of bevacizumab in salvage therapy for glioblastoma remains uncertain. The PBAC also considered that lowering the authority level for glioblastoma to Authority Required (STREAMLINED) could result in further growth in expenditure. The PBAC was cognisant that all other PBS indications for bevacizumab are Authority Required (STREAMLINED).