

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MAY 2023 PBAC MEETING**

The PBAC outcomes and recommendations are presented in alphabetical order by drug name.

Submission items

| DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION | DRUG TYPE AND USE | LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION | PBAC OUTCOME | |
|---|--------------------------------|---|--------------------|---|
| <p>CARMELOSE WITH GLYCEROL AND HYALURONIC ACID</p> <p>Eye drops containing carmellose sodium 5 mg with glycerol 9 mg and sodium hyaluronate 1 mg per mL, 10 mL</p> <p>Optive Fusion®</p> <p>Allergan Australia Pty Limited</p> <p>Matters outstanding (New PBS listing)</p> | <p>Severe dry eye syndrome</p> | <p>To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome.</p> | <p>Recommended</p> | <p>The PBAC recommended the listing of carmellose sodium 5 mg with glycerol 9 mg and sodium hyaluronate 1 mg per mL multidose preservative-containing eye drops (Optive Fusion) as a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome on a cost-minimisation basis to the lowest cost Pharmaceutical Benefits Scheme (PBS) listed ocular lubricant.</p> |
| <p>DAROLUTAMIDE</p> <p>Tablet 300 mg</p> <p>Nubeqa®</p> <p>Bayer Australia Ltd</p> <p>Matters outstanding (Change to PBS listing)</p> | <p>Prostate cancer</p> | <p>To request a General Schedule Authority Required listing, for use in combination with androgen deprivation therapy and docetaxel, for the treatment of metastatic hormone sensitive prostate cancer (mHSPC).</p> | <p>Recommended</p> | <p>The PBAC recommended darolutamide for the treatment of mHSPC. The PBAC noted that the advice from the Therapeutic Goods Administration (TGA) Delegate had been provided. The PBAC also noted that the proposal had:</p> <ul style="list-style-type: none"> • accepted the November 2022 recommended changes to the economic model, • provided revised financial estimates, and • proposed a restriction that mirrored the restriction previously recommended by the PBAC for apalutamide and enzalutamide which allowed darolutamide to be used as dual therapy in combination with androgen deprivation therapy (ADT) or as triple therapy in combination with ADT and docetaxel. <p>The PBAC considered that the risk sharing agreement (RSA) recommended for apalutamide should be amended to include docetaxel eligible patients who received triple therapy, as the darolutamide submission has proven the cost effectiveness of this combination in these patients.</p> |

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| <p>HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR</p> <p>Eye drops containing sodium hyaluronate 1.5 mg per mL with polyethylene glycol 400, propylene glycol and hydroxypropyl guar, 10 mL</p> <p>Systane® Hydration</p> <p>Alcon Laboratories (Australia) Pty Ltd</p> <p>Matters outstanding (New PBS listing)</p> | <p>Severe dry eye syndrome</p> | <p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</p> | <p>Recommended</p> | <p>The PBAC recommended the listing of hyaluronic acid with polyethylene glycol 400, propylene glycol, and hydroxypropyl guar (Systane Hydration) multi-dose preservative free eye drops as a treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops on a cost-minimisation basis to the lowest cost PBS listed ocular lubricant.</p> |
| <p>INCLISIRAN</p> <p>Injection 284 mg in 1.5 mL single use pre-filled syringe</p> <p>Leqvio®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>Early re-entry submission (New PBS listing)</p> | <p>Hypercholesterolaemia</p> | <p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia and atherosclerotic cardiovascular disease.</p> | <p>Recommended</p> | <p>The PBAC recommended inclisiran for the treatment of heterozygous familial hypercholesterolaemia (HeFH) and non-familial hypercholesterolaemia (non-FH) with atherosclerotic cardiovascular disease (ASCVD). The PBAC considered that the positioning of inclisiran as a third-line treatment as an alternative to the proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors (evolocumab and alirocumab) was appropriate. The PBAC considered the clinical effectiveness of inclisiran was comparable to evolocumab, although non-inferiority could not be confirmed due to the issues identified in March 2023. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of inclisiran would be acceptable if the cost minimised price to evolocumab was reduced by the discount offered in the resubmission. The PBAC noted that the resubmission had addressed the outstanding issues from the March 2023 submission and considered that the lower price offered in the cost minimisation approach and revised financial estimates were reasonable. The PBAC recommended potential flow on changes to the PBS restrictions for evolocumab and alirocumab to allow for switching between inclisiran and the PCSK9 inhibitors and to prevent concomitant use.</p> |

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Non-submission items

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|--|---|--|--------------------|--|
| <p>DASATINIB</p> <p>Tablet 20 mg Tablet 50 mg Tablet 70 mg Tablet 100 mg</p> <p>Multiple brands</p> <p>Multiple sponsors</p> <p>IMATINIB</p> <p>Capsule 100 mg (as mesilate) Capsule 400 mg (as mesilate) Tablet 100 mg (as mesilate) Tablet 400 mg (as mesilate) Tablet 600 mg (as mesilate)</p> <p>Multiple brands</p> <p>Multiple sponsors</p> <p>(Change to PBS listing)</p> | <p>Tyrosine kinase inhibitors (TKIs) for Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL)</p> | <p>To review the PBS restrictions for TKIs for Ph+ ALL in the maintenance setting.</p> | <p>Recommended</p> | <p>The PBAC recommended expanding the PBS restriction criteria for dasatinib and imatinib for the treatment of Ph+ ALL to allow subsidised access to 24 months of maintenance treatment if measurable residual disease (MRD) is not detected, and for ongoing treatment if MRD is detected. The PBAC noted that this will align the PBS restriction criteria with current clinical guidelines and is also consistent with clinical practice. The PBAC advised that the Induction and Consolidation phases should be limited to 6 months of treatment to allow patients to transition to maintenance treatment thereafter. The PBAC advised that the requirement for low dose chemotherapy or corticosteroids in the maintenance setting was not needed. The PBAC considered that the change in restriction criteria was unlikely to result in a substantial increase in the number of patients accessing dasatinib and imatinib through the PBS, and that it may reduce the number of patients transitioning to more costly treatment with blinatumomab.</p> |

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| <p>MULTI-COMPONENT MENINGOCOCCAL B VACCINE (RECOMBINANT, ADSORBED)</p> <p>Suspension for injection 0.5 mL pre-filled syringe</p> <p>Bexsero®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>(Change to listing)</p> | <p>Immunisation against invasive disease caused by N. meningitidis group B strains</p> | <p>To request advice from the PBAC on a proposal to make the Bexsero catch up program ongoing on the National Immunisation Program (NIP) for Aboriginal and Torres Strait Islander children.</p> | <p>Advice provided</p> | <p>The PBAC advised that it endorsed extending the NIP listing of meningococcal B vaccine (4CMenB) and supported a change from the current time-limited catch-up program to allow for an ongoing, routine catch-up program for First Nations children under 2 years old, consistent with advice from the Australian Technical Advisory Group on Immunisation.</p> |
| <p>OVERALL SURVIVAL IN PEOPLE RECEIVING PBS-SUBSIDISED CANCER MEDICINES IN AUSTRALIAN CLINICAL PRACTICE</p> <p>Multiple medicines</p> <p>Multiple brands</p> <p>Multiple sponsors</p> <p>(Post-market review)</p> | <p>Cancer</p> | <p>To consider the findings of the 'Protocol: Estimating overall survival in people receiving PBS-listed cancer medicines in Australian clinical practice' final report.</p> <p>To advise the Department if any further research should be undertaken on survival outcomes relating to PBS-listed cancer medicines or other medicines for non-cancer indications using the methods outlined in the protocol.</p> | <p>Noted</p> | <p>The PBAC recalled that at its December 2020 meeting it supported a proposal to develop and test a research protocol to robustly estimate overall survival (OS) in people receiving PBS-listed medicines for the treatment of advanced solid tumour cancers using PBS/real-world data.</p> <p>The PBAC considered the methods detailed in the final report titled 'Protocol: Estimating overall survival in people receiving PBS-listed cancer medicines in Australian clinical practice.'</p> <p>The PBAC advised that overall, the protocol was informing regarding the methods that are considered 'best-practice' when using PBS data to derive estimates of the survival outcomes attributed to specific cancer medicines. The PBAC considered that the methods detailed in the protocol may help inform other health technology assessment (HTA) research by contributing to the robust analysis of OS using PBS data linked to other clinical data in the future.</p> <p>The PBAC was supportive of further exploration into how this research could be extended to other cancer medicines and/or different medicine classes. The PBAC supported publication of the protocol as it may be informative to sponsors and evaluation groups involved in HTA research on the real-world use of medicines.</p> |

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| <p>PEMBROLIZUMAB</p> <p>Powder for I.V. infusion 100 mg (as disodium)</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>(Change to PBS listing)</p> | <p>Melanoma</p> | <p>To consider a request from the Melanoma Institute Australia (MIA) to expand the current PBS listings for pembrolizumab for the adjuvant treatment of resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma to allow neoadjuvant treatment.</p> | <p>Recommended</p> | <p>The PBAC noted the request from the MIA and recommended to amend the pembrolizumab restrictions to allow treatment in patients with Stage IIIB, Stage IIIC or Stage IIID melanoma in addition to complete surgical resection. The PBAC noted that the amendment is expected to result in minimal financial impact as there is no change to total treatment duration and cost. The PBAC advised that treatment in addition to complete surgical resection should be restricted to the 3 weekly regimen only.</p> |

Version 2

1. INCLISIRAN– web outcome updated to include potential flow on changes to the PBS restrictions.

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Resubmission pathways

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| <p>*There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC. The resubmission pathways are classified into the following categories:</p> | |
| Standard re-entry | <p>The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where:</p> <ul style="list-style-type: none"> ● an applicant chooses not to accept the PBAC nominated resubmission pathway; or ● an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or ● an applicant decides to lodge later than the allowable timelines for the other pathways. |
| Early re-entry pathway | <p>An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting.</p> |
| Early resolution pathway | <p>For medicines or vaccines deemed by the PBAC to represent HATV AND where the PBAC considers that the remaining issues could be easily resolved, including when:</p> <ul style="list-style-type: none"> ● new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and ● a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission. <p>Applicants who accept this pathway are eligible for PBAC consideration out-of-session (before the main meeting), unless the department, in consultation with the PBAC Chair, identifies an unexpected issue such that the resubmission needs consideration at the next main PBAC meeting.</p> |
| Facilitated resolution pathway | <p>A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop AND where the medicine or vaccine meets the HATV criteria. Applicants who accept this pathway are eligible for a solution-focussed workshop with one or more members of the PBAC. The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair.</p> |