

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
SEPTEMBER 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 style="text-align: center;">CABOTEGRAVIR</p> <p>Suspension for injection 600 mg in 3 mL</p> <p style="text-align: center;">Apretude®</p> <p style="text-align: center;">ViiV Healthcare Pty Ltd</p> <p>Matters outstanding (New PBS listing)</p>	<p>Pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV) infection</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for use as PrEP for HIV infection in persons in whom tenofovir disoproxil with emtricitabine (TD/FTC) is contraindicated.</p>	<p>Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required (STREAMLINED) listing of cabotegravir long-acting injection (CAB-LA) for HIV PrEP, on the basis that the revised restriction and price offer would achieve an equitable and acceptably cost-effective listing.</p> <p>The PBAC considered the revised restriction appropriately allows a simpler clinical assessment of whether an individual is likely to have compromised efficacy with oral PrEP and would experience a benefit from a long-acting injectable alternative.</p>
<p style="text-align: center;">PATISIRAN</p> <p>Solution concentrate for I.V. infusion 10 mg in 5 mL</p> <p style="text-align: center;">Onpattro®</p> <p style="text-align: center;">Alnylam Australia Pty Ltd</p> <p>Early resolution submission (New PBS listing)</p>	<p>Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)</p>	<p>A resubmission requesting the listing of patisiran for the treatment of hATTR amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation for patisiran for the treatment of patients with hATTR amyloidosis with polyneuropathy to allow for further consultation with the sponsor. In deciding to defer making a recommendation, the PBAC reaffirmed its view that there was a high clinical need for effective treatments for this patient population, however the PBAC considered that further consultation with the sponsor was required regarding a cost-effective price for patisiran and addressing the uncertainty with the cost-effectiveness estimates (through a Managed Access Program) and the financial estimates (through a Risk Sharing Arrangement).</p> <p><u>Sponsor's Comment:</u> The sponsor had no comment.</p>

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<p style="text-align: center;">TEBENTAFUSP</p> <p>Solution concentrate for I.V. infusion 100 mcg in 0.5 mL vial</p> <p style="text-align: center;">Kimmtrak®</p> <p style="text-align: center;">Synevi Pty Limited</p> <p>Early resolution submission (New PBS listing)</p>	<p>Advanced (unresectable or metastatic) human leukocyte antigen (HLA)-A*02:01-positive uveal melanoma</p>	<p>A resubmission requesting the listing of tebentafusp for the treatment of HLA-A*02:01-positive adult patients with advanced (unresectable or metastatic) uveal melanoma.</p>	<p>Recommended</p>	<p>The PBAC recommended tebentafusp be listed on the PBS as a Section 100 (Efficient Funding of Chemotherapy) item for the treatment of HLA-A*02:01-positive adult patients with advanced (unresectable or metastatic) uveal melanoma. The PBAC recalled that it had previously noted the high unmet clinical need for new treatments in this setting and had considered that tebentafusp was superior compared to pembrolizumab in terms of efficacy, but likely inferior in terms of safety. The PBAC considered that the resubmission's changes to the proposed restrictions, economic model and financial impact estimates adequately addressed its previous concerns and considered that tebentafusp would be acceptably cost-effective at the price proposed in the resubmission.</p>
<p style="text-align: center;">SOMATROPIN</p> <p>Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative) Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)</p> <p style="text-align: center;">Saizen®</p> <p style="text-align: center;">Merck Healthcare Pty Ltd</p> <p>Category 3 submission (Change to PBS listing)</p>	<p>Severe late onset growth hormone deficiency (GHD)</p>	<p>To extend the PBS listing of somatropin solution for injection 6 mg (18 i.u.) in 1.03 mL and 12 mg (36 i.u.) in 1.5 mL (Saizen®) to include the treatment of severe late onset GHD.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of somatropin solution for injection 6 mg (18 i.u.) in 1.03 mL and 12 mg (36 i.u.) in 1.5 mL on a cost-minimisation basis for the treatment of severe late onset GHD on the basis that it should be available only under special arrangements under Section 100 (Growth Hormone Program), and under the same circumstances as somatropin products currently PBS-listed for this indication. The PBAC recalled its previous recommendation in July 2017 to list somatropin for severe late onset GHD. It noted that three brands of somatropin are currently PBS-listed as a result of this recommendation, however, one brand will be discontinued next year, and one brand is experiencing a supply shortage. The PBAC therefore considered there was a clinical need to list an additional brand of somatropin on the PBS for this indication. The PBAC considered the equi-effective doses to be 1 mg of Saizen and 1 mg of other somatropin products PBS-listed for this indication and considered that all the different brands of somatropin are considered equivalent on a per mg basis.</p>

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Non-submission items

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<p>CHORIOGONADOTROPIN ALFA</p> <p>Solution for injection 250 micrograms in 0.5 ml, pre-filled pen</p> <p>Ovidrel®</p> <p>Merck healthcare Pty Ltd</p> <p>(Change to PBS listing)</p>	<p>Infertility indications other than that of Assisted Reproductive Technology (ART)</p>	<p>To consider the request to increase the maximum quantity of choriogonadotropin alfa (Ovidrel®) that is listed on the PBS as a Section 85 (S85) General Schedule listing for infertility indications other than that of ART.</p>	<p>Recommended</p>	<p>The PBAC recommended increasing the maximum quantity of Ovidrel that is currently listed on the PBS as a General Schedule Restricted Benefit for infertility indications other than that of ART to 4 pens, to allow for sufficient quantity for 1 month of treatment at standard doses. The PBAC noted standard induction doses required the use of one Ovidrel pen every 2 weeks and approximately half of patients using Ovidrel for infertility indications other than that of ART would require up to 4 Ovidrel pens per month. The PBAC noted the change to the listing is not expected to change utilisation or the patient population. However, it may result in a financial impact on Government due to the difference in dispensing fees, mark-ups and changes in the number of patient co-payments, which the PBAC considered to be acceptable.</p>
<p>HYDROCORTISONE</p> <p>Capsule containing granules 0.5 mg</p> <p>Capsule containing granules 1 mg</p> <p>Capsule containing granules 2 mg</p> <p>Capsule containing granules 5 mg</p> <p>Alkindi®</p> <p>Chiesi Australia Pty Ltd</p> <p>(Matters arising)</p>	<p>Adrenal insufficiency in children aged 6 or younger</p>	<p>Review of positive PBAC recommendations not accepted by applicants</p>	<p>Recommended</p>	<p>The PBAC advised that the recommendation be extended for an additional 6 months.</p>

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<p>METHOTREXATE</p> <p>Tablet 2.5 mg, Tablet 10 mg</p> <p>Injection 5 mg in 2 mL vial, Injection 50 mg in 2 mL vial</p> <p>Injection 7.5 mg in 0.15 mL pre-filled syringe Injection 10 mg in 0.2 mL pre-filled syringe Injection 15 mg in 0.3 mL pre-filled syringe Injection 20 mg in 0.4 mL pre-filled syringe Injection 25 mg in 0.5 mL pre-filled syringe</p> <p>Methoblastin® DBL™ Methotrexate Trexject®</p> <p>Pfizer Australia Pty Ltd Link Medical Products Pty Ltd</p> <p>(Change to PBS listing)</p>	<p>Rheumatological conditions</p>	<p>To seek the advice of the PBAC on a request to change the current PBS listings of low-dose methotrexate for the management of rheumatological conditions to include nurse practitioners (NPs) as eligible prescribers.</p>	<p>Recommended</p>	<p>The PBAC recommended amending the current PBS listings of low-dose methotrexate used for the management of rheumatological conditions to include NPs as eligible prescribers. The PBAC noted its intention was for the recommendation to apply to those NPs who have undertaken specific training in managing rheumatological conditions and who are approved for prescribing low-dose methotrexate. The PBAC considered allowing rheumatology NPs to prescribe low-dose methotrexate could improve patient access to the medicine.</p>

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<p style="text-align: center;">Zoledronic acid</p> <p style="text-align: center;">Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL</p> <p style="text-align: center;">APO-Zoledronic Acid</p> <p style="text-align: center;">Apotex Pty Ltd</p> <p style="text-align: center;">(Matters Outstanding)</p>	<p style="text-align: center;">Adjuvant management of breast cancer in post-menopausal women</p>	<p style="text-align: center;">To seek PBAC advice on a potential addendum to the December 2022 minutes for zoledronic acid for the adjuvant management of breast cancer in post-menopausal women.</p>	<p>Advice provided</p>	<p>The PBAC noted that APO-Zoledronic Acid has been approved for use for the adjuvant management of breast cancer in post-menopausal women by the Therapeutic Goods Administration (TGA) and recalled its previous recommendation in July 2023 to amend the PBS-listing of APO-Zoledronic acid to include this indication. The PBAC noted that following this recommendation, the sponsor of APO-Zoledronic Acid has advised that it will be unable to supply the product to market.</p> <p>The PBAC noted that no other brands of zoledronic acid 4 mg in 5 mL are currently TGA-approved for this indication.</p> <p>The PBAC advised that, consistent with its July 2023 recommendation, it considered that any brand of zoledronic acid 4 mg in 5 mL would be effective and cost-effective in the adjuvant management of breast cancer in post-menopausal women at the existing PBS price, provided that brand had been registered by the TGA for use in this indication.</p>

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Resubmission pathways

<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>