5.23 ESTRADIOL WITH PROGESTERONE
Capsule containing estradiol 1mg (as hemihydrate) with progesterone 100mg, BIJUVA®, Theramex Australia Pty Ltd.

1 Purpose of submission

1.1 The Category 3 submission requested reconsideration of the PBAC's November 2025 recommendation to list estradiol 1 mg (as hemihydrate) with progesterone 100 mg (hereinafter referred to as Bijuva®) as a General Schedule Unrestricted Benefit listing and a corresponding General Schedule Restricted Benefit listing for 60-day maximum dispensed quantities (MDQ) for the treatment of moderate to severe vasomotor symptoms (VMS) in postmenopausal women.

1.2 The submission requested a revised price based on a weighted price calculated using the price of Estrogel Pro and the individual oral components.

1.3 The submission proposed a lower price than that requested in November 2025. However, the submission stated that if a statutory price reduction for progesterone 100 mg was applied and subsequently affected the price of Bijuva the sponsor would decline to list (p.vi of the submission).

1.4 The submission presented a revised PICO table as shown in Table 1. A summary of the key matters of concern addressed in the submission is presented in Table 2.

Table 1: Key components of the clinical issue addressed by the submission (as stated in the submission)

Component	July 2026 Submission	November 2025 Submission
Population	Postmenopausal women with an intact uterus experiencing estrogen deficiency symptoms. Women must not have risk factors for VTE development (e.g. prior VTE history, obesity).	Postmenopausal women with an intact uterus experiencing estrogen deficiency symptoms
Intervention	Bijuva (estradiol hemihydate and micronised progesterone) oral capsules, 1mg/100mg	Bijuva (estradiol hemihydate and micronised progesterone) oral capsules, 1mg/100mg
Comparator	Primary: Estrogel Pro (Estrogel 0.06% (estradiol hemihydrate) gel pump pack with Prometrium 100mg (micronised progesterone) oral capsules Secondary: Oral estradiol and progesterone taken concomitantly Progynova (estadiol valerate) 1 mg tables Prometrium 100mg (micronised progesterone) oral capsules	Estrogel Pro (Estrogel 0.06% (estradiol hemihydrate) gel pump pack with Prometrium 100mg (micronised progesterone) oral capsules

Component	July 2026 Submission	November 2025 Submission
Outcomes	Key Bijuva and (Estrogel Pro) trial outcomes (and results) unchanged from previous submission. Additional clinical data is provided in response to PBAC requests for additional information. Relevant outcomes include: • Compliance/adherence and discontinuation rates by MHT type/administration route. • Endometrial safety (incidence of endometrial hyperplasia) • Unscheduled bleeding episodes. • Quality of life improvements (MENQOL) • Sleep quality improvements (MOS-Sleep Scale) • Overall safety and tolerability	Primary: • Reduction in frequency of moderate to severe VMS at Week 4 and Week 12 • Reduction in severity of moderate to severe VMS at Week 4 and Week 12 • Endometrial safety (incidence of endometrial hyperplasia at 12 months) • Secondary: • Quality of life improvements (MENQOL) • Sleep quality improvements (MOS-Sleep Scale) • Overall safety and tolerability
Clinical claim	Bijuva vs. oral estradiol plus progesterone (administered as separate oral components) has non-inferior effectiveness and superior safety in the re-defined population: • non-inferior effectiveness at treating estrogen deficiency symptoms • superior safety from increased compliance with progesterone dosing from FDC (resulting in reduced risk for endometrial hyperplasia development, and comparable safety with other MHT risks). Bijuva vs. Estrogel Pro have non-inferior effectiveness and at least non-inferior safety in the re-defined population (i.e. in patients not at risk of VTE disease) • at a minimum non-inferior safety (due to reduced risk for endometrial hyperplasia development, and comparable safety with other MHT risks).	Bijuva (combination estradiol-progesterone oral capsules) is non-inferior to Estrogel in treating estrogen deficiency symptoms in postmenopausal women, based on indirect comparison methodology.

Source: Table ES.1 pp ii-iii of the submission.

2 Background

Previous PBAC consideration

2.1 The PBAC recommended Bijuva for PBS-listing in November 2025. The PBAC advised that the claim of non-inferior efficacy for Bjiuva against Estrogel Pro was adequately supported, but that insufficient evidence was provided to justify a price premium for Bijuva, as a fixed dose combination product, over the sum of the individual prices of an existing oral estradiol product and progesterone, and listing should be on a cost minimisation basis against estradiol valerate 1 mg tablet (28 days) and progesterone 100 mg capsule (25 days out of a 28-day cycle) (Paragraphs 7.5, 7.7, estradiol with progesterone Public Summary Document [PSD], November 2025 PBAC Meeting).

2.2 The PBAC also noted that it was generally accepted that the risk of thrombo-embolic disease is greater with oral than with topical estradiol and that for this reason the claim that Bijuva had non-inferior safety compared to Estrogel Pro was not adequately supported (Paragraph 7.5, estradiol with progesterone PSD, November 2025 PBAC Meeting).

2.3 The matters of concern and the submission's responses are shown in Table 2.

Table 2: Summary of key matters of concern

Component	Matter of concern	How the submission addresses it
Clinical claim of non-inferior safety vs Estrogel Pro.	Oral estradiol has a greater risk of VTE compared to topical estradiol (Para 7.5 November 2025 PSD).	Addition to eligible population: "Women must not have risk factors for VTE development (e.g. prior VTE history, obesity)".
Clinical place in therapy.	No evidence justifying higher price versus oral components used concomitantly (Para 7.7, November 2025 PSD).	Claim of superior safety from increased compliance with progesterone from FDC.

Source: Constructed during the evaluation using Table ES.1, ppii-iii of the submission.
FDC = fixed dose combination; VTE = venous thrombo-embolism.

3 Requested listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	DPMQ	Available brands
ESTRADIOL + PROGESTERONE						
estradiol 1 mg + progesterone 100 mg capsule, 28	NEW MP NP	1	28	5	$[redacted]	Bijuva
Category / Program: ☒ GENERAL - General Schedule (Code GE)						
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners						
Restriction type: ☒unrestricted benefit						

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	DPMQ	Available brands
ESTRADIOL + PROGESTERONE						
estradiol 1 mg + progesterone 100 mg capsule, 28	NEW MP NP	2	56	5	$[redacted]	Bijuva
Category / Program: ☒ GENERAL - General Schedule (Code GE)						
Prescriber type: ☒Medical Practitioners ☒Nurse practitioners						
Restriction type: ☒ Restricted benefit						
	Indication: The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.					

3.1 No changes to the November 2025 recommended listing were requested. The submission did not specifically propose a listing restricting access to patients without risk factors for VTE.

4 Comparator

4.1 The submission nominated as comparators Estrogel Pro (co-pack of estradiol transdermal gel plus oral progesterone) and oral estradiol valerate with oral progesterone packaged separately. The addition of the separate estradiol and progesterone components of Bijuva as comparators was a change from the previous submission.

4.2 The comparator of separate estradiol and progesterone was appropriate, because they are the same active ingredients, and the principal claim made by the submission is that it is Bijuva's combining them as a FDC that is beneficial.

4.3 The PBAC has previously considered that transdermal estradiol should not be a comparator for oral estradiol because of a higher risk of VTE with oral versus transdermal estradiol, (Paragraph 7.5, estradiol with progesterone PSD, November 2025 PBAC Meeting).

4.4 The submission suggested restricting use to women who do not have an increased risk of VTE would mitigate the safety concern and that topical estradiol would therefore be an appropriate comparator for oral estradiol. The submission did not specify how prescribing of Bijuva could be limited to patients without risk factors for VTE in clinical practice. The pre-PBAC response stated that in routine clinical practice prescribing of MHT is inherently risk-stratified, with prescribers assessing VTE risk factors, including prior history, obesity, and comorbidities, prior to initiation.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 There were no consumer comments for this item.

Clinical trials

5.3 No trial data was presented other than that reviewed by the PBAC in November 2025.

5.4 The submission presented a comparison of Bijuva versus the oral components taken concomitantly and a comparison versus transdermal estradiol and concomitant but co-packaged progesterone. The submission provided a summary of the following matters 1) How Bijuva addresses a treatment gap (with reference to the National Women's Health Strategy) 2) Patient groups benefiting from Bijuva over the nominated comparators 3) A Justification for comparability of oral and transdermal MHTs. The claims made in the submission relating to these matters are summarised in Table 3.

Table 3: Overview of issues addressed in the submission

Treatment Comparison	Issues	Response of Submission	Comments

Bijuva versus estradiol 1 mg and progesterone 100 mg daily	How Bijuva addressed a treatment gap with reference to National Women's Health Strategy (NWHS)	- Improved affordability with a single PBS co-payment - improving equity and affordability, removing financial barriers to care;
		- Quality of life (QoL) benefits: Bijuva has high quality RCT data showing improved QoL and sleep outcomes – QoL a key outcome to women, cited in NWHS;
		- Learning from international best practice to provide best care, filling MHT service gaps:
		  - Lack of clinical data supporting oral component proposed comparator; Bijuva is a modern formulation that has overcome constituent formulation challenges to provide FDC;
		  - Lack of choice with oral MHT, no body-identical FDC;
		  - Reduction in endometrial hyperplasia/cancer risk with continuous MP vs. non-continuous use – Bijuva is the only FDC guaranteeing concomitant use of estradiol + MP administered appropriately.
			The difference in copayments is less than that presented in the submission and some alternatives would be cheaper (para 6.3-5).
			Benefits to QoL and sleep are marginal and of uncertain significance.
			
			Incorrect as regards evidence base for comparator..
			
			Value of body-identical FDC unsupported by evidence.
			
			Claim of reduced endometrial cancer risk not supported by evidence.

	Patient groups benefiting from Bijuva over individual oral components	- Older Australian women requiring affordable MHT care – 1 PBS co-payment; - Preferring a convenient FDC with a simple dosing regimen to enhance compliance/adherence; - Women concerned with endometrial cancer risk: - reduced risk for endometrial hyperplasia supported by FDC with continuous MP dosing, ensuring clinically proven estradiol:MP dosing ratio/regimen	*Not supported by evidence.* *Not supported by evidence.*
	Therapeutic claims	Bijuva vs. individual oral components: - Bijuva provides non-inferior effectiveness at improving estrogen-treated menopause vasomotor symptoms. - Bijuva provides at least non-inferior safety – due to reduced risk of endometrial hyperplasia with guaranteed continuous MP component (and has comparable safety with other parameters).	*Non-inferior effectiveness - Agreed.* *Claim of reduced risk of endometrial hyperplasia not adequately supported by evidence).*

Treatment Comparison	Issues	Response of Submission	Comments
Bijuva vs. Estrogel Pro	Clinical place of Bijuva	Supported by multiple local/international menopause management guidelines, Bijuva PI, REPLENISH RCT: - Clinical place in women requiring MHT not at risk for development of VTE disease (e.g. no VTE history, non-obese) - International Menopause Society (IMS) Guidelines: "If there are no particular risk factors (e.g. obesity, history of VTE) there is little reason why oral estrogen could not be prescribed. Patient-informed choice should always prevail." - REPLENISH RCT was in this 'otherwise healthy' population, i.e. not at risk for VTE, providing high quality data supporting clinical effectiveness and safety in the clinically indicated group.	*Non-obese women with no VTE history are still at increased risk of VTE with oral vs topical estradiol). A further issue is whether women at increased risk can be identified in practice..* *Trial exclusions more stringent that proposed restriction but VTE in estradiol-treated patient observed.*

	Patient groups benefiting from Bijuva over Estrogel Pro	- Individualised treatment and choice: FDC preferred by some women
		- Transdermal MHT unsuitable (in oral MHT indicated women) due to:
		  - Inadequate response – difficult to predict response due to variation in serum concentration (can vary by a factor of 10);
		  - Estrogel has administration limitations that may reduce effectiveness and adherence – must dry prior to dressing, unable to wash/shower after administration, risk of transfer to others;
		- Providing viable options to transdermal treatments – long-term and ongoing transdermal MHT shortages;
		- Issues with inadequate response, adverse effects, tolerability to transdermal should be reviewed after 3 months, with change in formulation a potential treatment option (ESE recommendation);
		- Unscheduled bleeding higher with transdermal vs. oral combination MHT
			No evidence was presented that women prefer FDC.
			
			These statements are correct, but there are alternative treatments other than Bijuva that address these issues and may be less expensive.
			
			This statement applies to all MHT.

Treatment Comparison	Issues	Response of Submission	Comments
	Therapeutic claims	- Bijuva vs. Estrogel Pro in the population who is not at risk for development of VTE disease - Bijuva provides non-inferior effectiveness at improving estrogen-treated menopause vasomotor symptoms. - Bijuva provides at least non-inferior safety – due to reduced risk of endometrial hyperplasia with guaranteed continuous MP component (and has comparable safety with other parameters including VTE risk in the selected population).	*PBAC previously agreed that Bijuva provides non-inferior effectiveness.* *Claim regarding endometrial hyperplasia not supported by evidence).* *Claim regarding VTE risk not justified because non-obese women with no VTE history are still at increased risk of VTE with oral vs topical estradiol.. Further issue is whether women at increased risk can, in practice, be identified.*
	Justification for comparability of oral and transdermal MHTs	- Provides comparable effectiveness in the selected population indicated for oral combined MHT (PBAC assessed data/recommendation). - Comparable or improved safety in the indicated population, including continuous MP administration guaranteeing reduced endometrial hyperplasia risk. - Treatment option following failure of transdermal MHT in indicated population - Treatment option for those unable to tolerate transdermal MHT in indicated population - Higher compliance with oral vs. transdermal MHT demonstrated, supporting appropriate use for maximum effectiveness in practice. - Provides modern, best practice therapy option - supporting quality use of medicines, MHT treatment guidelines and goals of NWHS and Senate Inquiry.	*Agreed.* *Not supported by evidence.* *Correct but other equally effective options may be cheaper.* *Correct only if intolerance is not due to adverse effects of progesterone, and other equally effective options may be cheaper.* *Not correct.* *Not supported.*

Source: Modified from Table 1-1, pp5-6 of the submission.
FDC = fixed-dose combination; MHT = menopausal hormone therapy; MP = micronised progesterone; NWHS = National Women's Health Strategy; VTE = venous thromboembolism.

5.5 The pre-PBAC response reiterated that Bijuva addresses an unmet need, the absence of an oral fixed-dose combination of body-identical estradiol and progesterone in the Australian market. The pre-PBAC stated that current treatment options require women to either:

- use transdermal therapy, which may be unsuitable (due to adverse e vents, intolerance, inadequate response); or
- manage separate oral or co-prescribed products, which introduces adherence complexity.

5.6 The pre-PBAC response state that Bijvua resolves this gap and aligns with both clinical guidelines and broader policy objectives to improve access, adherence, and patient-centred care in menopause management.

Discussion of claims made by the submission

Financial Burden/Affordability

5.7 The claim of improved affordability was based on the need for two PBS co-payments for concomitant estrogen and progesterone versus one for Bijuva. The claim was accepted in principle by the PBAC in November 2025 (Paragraph 7.2, estrogen with progesterone PSD, November 2025 PBAC Meeting).

5.8 The DPMQ for estradiol valerate 1 mg is $[redacted] for 56 tablets, and the private prescription price is currently approximately $9.00 and $7.10 for concession card holders. While in principle it seems as though patients will pay one less co-payment per month, the actual additional out of pocket expense for a general patient is approximately $[redacted] per month for estradiol 1 mg and progesterone 100 mg vs Bijuva. For concession patients the additional cost is approximately $[redacted] per month.

Evidence for the efficacy of comparators

5.9 No new evidence was provided. There is no meaningful difference in the quality of evidence relevant to the submission's claim that Bijuva is non-inferior to oral estradiol and progesterone taken separately with regard to efficacy in the treatment of VMS.

5.10 When the PBAC considered the data for efficacy of Bijuva in the treatment of VMS in November 2025 it noted that in the REPLENISH trial the least squares mean change (95% CI) in the weekly frequency of moderate to severe VMS episodes versus placebo was -16.6 (-23.3, -9.8) (Table 4, estrogen with progesterone PSD, November 2025 PBAC Meeting). A Cochrane review of oral estrogen treatment identified nine trials of adequate quality in 2004 patients which included outcome data for VMS. The weighted mean difference (95% CI) in the weekly frequency of VMS was -17.9 (-22.9, -13.0).[1]

5.11 The submission claimed that no trials showing that estradiol and progesterone taken separately improved sleep or quality of life had been identified, however, that the REPLENISH study established that Bijuva did improve those outcomes.

5.12 REPLENISH found that Bijuva was associated with statistically and marginally clinically significant improvements in the MENQOL vasomotor domain; the mean difference versus placebo was -1.2 at 12 months, with the minimal clinically important difference -1.0. However, there were no clinically significant differences versus placebo in the overall MENQOL score at any time point (Archer, 2019). In November 2025, PBAC noted that these results were also compromised by "uncertainty in the construct

[1] MacLennan AH, Broadbent JL, Lester S, Moore V. Oral oestrogen and combined oestrogen/progestogen therapy versus placebo for hot flushes. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD002978. DOI: 10.1002/14651858.CD002978.pub2.

validity and test-retest reliability of the vasomotor domain" (Paragraph 6.38, estradiol with progesterone PSD, November 2025 PBAC Meeting).

5.13 In November 2025 PBAC noted that "the MOS Total Sleep Score reported statistically significant improvement with Bijuva compared to placebo at Week 12 and Month 6; however, such improvement was not statistically significant at Month 12, with reported LS mean change from placebo of -4.6 (95% CI: -9.4, 0.2)" and that "[n]o significant differences were reported for the following domains: Sleep adequacy, sleep somnolence, and optimal sleep, at all three time points" (Paragraph 6.39, estradiol with progesterone PSD, November 2025 PBAC Meeting).

5.14 Two systematic reviews of the efficacy of MHT for sleep disturbance were cited by the submission as not providing RCT evidence of an effect on sleep of estradiol 1 mg oral (Progynova) tablets.

5.15 Pan, 2022, reported that estrogen monotherapy improved subjective sleep quality but not sleep parameters measured by polysomnography, that combined estrogen and progesterone (however it was delivered) reduced sleep disturbance, and that topical MHT was more effective than oral MHT.

5.16 Nolan, 2021, reviewed only trials comparing micronised progesterone with placebo or an active comparator. The evaluation did not consider this study to be relevant.

5.17 The relevance of the claims concerning quality of evidence is limited, because the submission made a claim of non-inferiority and stated that given that both Bijuva and Progynova contain estradiol 1 mg taken daily, non-inferior effectiveness from the estradiol component is assumed.

Reduced risk of endometrial hyperplasia and carcinoma

5.18 The submission claimed that Bijuva will have superior safety to the components taken concomitantly, whether prescribed separately or co-packaged as Estrogel Pro because women treated with Bijuva are likely to have greater adherence to the appropriate combination of Estrogel and progesterone, thus reducing their overall risk of endometrial hyperplasia.

5.19 There were two elements to this claim: first, that patients who take estradiol and sequential progesterone (usually 10-12 days per cycle at 200 mg per day) for long periods may have a higher risk of endometrial hyperplasia and endometrial cancer, and, second, that compliance will be less with concomitant estradiol and progesterone than with Bijuva, to such an extent that prescribing concomitant estradiol and progesterone amounts to prescribing sequential combined MHT.

Risk with sequential versus continuous MHT

5.20 The submission did not include consideration of duration of use/exposure in its presentation of the risks of endometrial hyperplasia/carcinoma from continuous and sequential use of MHT. Evidence from randomised controlled trials, not cited in the submission, shows that sequential combined MHT is as effective as continuous

combined MHT in preventing endometrial hyperplasia for up to five years.[2] The claim that Bijuva would have superior safety because it will prevent endometrial carcinoma in women who miss progesterone doses was not adequately justified for women taking MHT for less than 5 years.

5.21 The submission stated (p23) that the NICE Guidance NG23 (2024) had ″assessed the risk of endometrial cancer to be lower with use of continuous combined MHT (which FDC Bijuva provides) compared with both no use of MHT and compared with use of sequential combined MHT (e.g. Progynova + Prometrium and Estrogel Pro, where continuous use of MP cannot be ensured)". The submission did not distinguish between use for less than five years and longer-term use, and conflated sequential combined MHT with use of separately administered estradiol and progesterone.

5.22 The NICE Guidance NG23 (2024) states that in women taking MHT "some observational evidence suggested an important harm for incidence of endometrial cancer with sequential combined HRT in current users with 10 or more years of use, but no difference in the risk with less than 10 years use" (p18, NICE Guideline NG23, Menopause [update] [E] Endometrial cancer).

5.23 A study of the Danish prescription registry (N = 914,595 women) found a relative risk (95% CI) of endometrial cancer compared to never MHT of 2.06 (1.88, 2.27) for sequential combined MHT and 1.02 (0.87, 1.20) for continuous combined MHT.[3] A study nested within an NIH cohort study of retired persons (N = 19,131 women) found a relative risk (95% CI) of endometrial cancer compared to never MHT of 1.88 (1.36, 2.60) for sequential combined MHT used for 10 years or longer, 0.90 (0.64, 1.27) for sequential combined MHT used for less than 10 years, and 0.64 (0.49, 0.83) for continuous combined MHT.[4] A study nested within a European cohort study of nutrition and cancer (N = 115,474) found a hazard ratio (95% CI) for endometrial cancer in users of combined MHT versus never users of 1.41 (1.08, 1.83), for sequential combined MHT of 1.52 (1.00, 2.99) and for continuous combined MHT of 0.24 (0.08, 0.77).[5] However, data for the MHT regimen (continuous vs sequential) was missing for 39% of women who had used combined MHT and for >80% of women in Italy, France and Spain but for <5% in Denmark, Norway and the UK. The NICE Guideline NG23, Menopause [update] [E] Endometrial cancer includes reference to these studies.

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[2] Stute P, Neulen J, Wildt L. The impact of micronized progesterone on the endometrium: a systematic review. *Climacteric*, 2016; *19*: 316–328.

[3] Mørch LS, Kjaer SK, Keiding N, Løkkegaard E, Lidegaard Ø. The influence of hormone therapies on type I and II endometrial cancer: A nationwide cohort study. *Int J Cancer* 2016; 138:1506-15.

[4] Trabert B, Wentzensen N, Yang HP, et al. Is estrogen plus progestin menopausal hormone therapy safe with respect to endometrial cancer risk? *Int J Cancer* 2013; 132: 417-426.

[5] Allen NE, Tsilidis KK, Key TJ, et al. Menopausal hormone therapy and risk of endometrial carcinoma among postmenopausal women in the European Prospective Investigation into Cancer and Nutrition. *Am J Epidemiol* 2010; 172:1394-1403.

5.24 As part of advice regarding the risk of endometrial cancer in MHT users who do not report unscheduled bleeding the British Menopause Society states that "[w]omen taking a sequential preparation (sHRT) over the age of 45 should be offered, after five years of use or by age 54 (whichever comes first), a change to ccHRT" (British Menopause Society 2024b, p12; cc = continuous combined).

5.25 *The PBAC noted that the Australian Therapeutic Guidelines - Sexual and Reproductive Health – Menopause states that observational data suggest that long-term use of cyclical combined MHT is associated with an increased risk of endometrial cancer compared to continuous combined MHT and advises that cyclical MHT should be reviewed after 5 years and consider switching to continuous combined MHT.*

5.26 The recommendation of the NICE and the British Menopause Society guidelines that women should not continue sequential combined MHT for more than five years is not echoed by other international guidelines (Lumsden, 2025; North American Menopause Society, 2022; Davis, 2023b).

Treatment adherence with Bijuva versus the components taken separately

5.27 The submission presented several arguments in support of the claim that compliance would be meaningfully better with Bijuva than with concomitant estradiol and progesterone.

5.28 The submission cited the British Menopause Society's (BMS) Guideline on Management of Unscheduled Bleeding on Hormone Replacement Therapy (HRT) (British Menopause Society 2024b) as having "specifically identified poor compliance with non-combined preparations as a reason to change to a combined oral preparation like Bijuva".[6]

5.29 This may suggest that the guideline supports the view that compliance with non-combined preparations is likely to be poor and that for this reason a combined oral preparation is preferrable, however this is incorrect. The BMS guideline states that in women with unscheduled bleeding where non-compliance is identified as the likely cause, there are several reasonable options: changing to a combined topical preparation; changing to a combined oral preparation; making adherence easier, by, e.g., telephone reminders, or suggesting to women using topical estradiol and oral progesterone that they take the progesterone at the same time as they apply the gel; offering a levonorgestrel IUD (p29). Note, levonorgestrel IUD is not listed on the PBS for MHT.

5.30 The guideline does not recommend combined oral preparations in preference to alternatives such as oral estradiol and oral progesterone or topical estradiol and oral progesterone in women without unscheduled bleeding (British Menopause Society 2024b, pp12-16).

[6] The resubmission attributed this to the British Menopause Society Consensus Statement on Bioidentical HRT (British Menopause Society, 2024a), but that seems to have been a citation error.

5.31 The circumstance of non-adherence to progesterone being a result of adverse effects, the commonest of which is mood changes associated with progesterone is not included in this statement. In this case changing to a combined oral preparation, such as Bijuva, would not be reasonable.

5.32 The submission referred to the BMS Consensus Statement on Bioidentical HRT (British Menopause Society, 2024a) as supporting the use of a FDC in preference to either oral estradiol and progesterone taken separately or topical estradiol with co-packaged oral progesterone. The submission quoted "Endometrial protection and avoidance of breakthrough bleeding may not be as consistent with separately administered oral MP as it is with standard oral continuous combined regimens. However, this may be partly due to lack of compliance due to the requirement for MP to be used separately with estrogen".

5.33 The submission also argued that as Bijuva is a FDC, compliance can be assumed to be better than with the components taken separately.

5.34 No systematic review of evidence was presented to support this claim. Two papers were cited: a position paper concerning the "polypill" - a FDC of antihypertensive, lipid lowering, antidiabetic and antiplatelet medications for primary prevention of cardiovascular disease (Coca, 2017) - and a non-randomised retrospective cohort study of anti-retroviral treatment (Sutton, 2016). The evaluation considered that these papers were not relevant, since they were of low quality and concerned different treatments in different populations.

5.35 A third line of argument was based on studies of the proportion of women who continued to be prescribed or in some cases to fill prescriptions for various forms of MHT over periods of years.

5.36 Data on prescriptions written or filled may not accurately assess the proportion of the prescribed dose actually taken, the aspect of use relevant to the submission's argument. Data on prescriptions filled usually would be considered a more reasonable estimate than prescriptions written.

5.37 Prescription data for MHT may be difficult to interpret because of the effect of the Million Women study and the Women's Health Initiative (WHI) study published in 2002, which found high risks of serious adverse events with MHT and resulted in sharp falls in the use of MHT. For example, in Australia use of MHT peaked in 2001 and had declined by 67% by 2008.[7] Recent evidence demonstrating the safety of MHT for younger women with troublesome menopausal symptoms has led to increased use of MHT, but treatment now is more likely to be relatively short-term and more likely to use topical preparations than before the MWS/WHI. For this reason, an association

[7] Salagame U, Kliewer EV, Demers A, et al. Trends in prescribing menopausal hormone therapy and bisphosphonates in Australia and Manitoba, Canada and adherence to recommendations. *J Womens Health (Larchmt)* 2020; 29:177-186.

between oral treatment and longer duration of treatment is likely in studies covering the periods before and after the MWS/WHI.

5.38 For example, in the study cited in the submission by Andrews (2025), which covered the period 1996-2023, women prescribed topical preparations were more likely to have stopped using MHT after one year, but women starting MHT before the MWS/WHI were more likely to continue use beyond one year and more likely to be prescribed an oral preparation.

5.39 The submission cited Shmuely (2003) as finding an oral MHT persistence rate of 83% at one year and Kyvernitakis (2015) as finding a topical MHT persistence rate at one year of "about 50%". A comparison of persistence using Shmuely, 2008 was inappropriate because this was not a study of routine clinical use but a meta-analysis of data on treatment discontinuation in clinical trials, where a higher rate of adherence than in routine use would be expected. Kyvernitakis (2015) reported a continuation rate for topical MHT of 39%, but found no difference between persistence with oral MHT using 1 mg estradiol and topical MHT (persistence with 2 mg oral estradiol was lower).

5.40 The submission also referred to the similarity of discontinuations in the Bijuva and placebo arms of the REPLENISH study (30.5% vs 31.1%) as showing that Bijuva has a tolerable profile that does not lead to excess discontinuations. However, 30% is a high rate of discontinuation in a randomised controlled trial, and discontinuations due to adverse events were more common in the Bijuva-treated group than in the placebo group (Paragraph 6.47, estradiol with progesterone PSD, November 2025 PBAC Meeting).

Safety of Bijuva versus topical estradiol when women at increased risk of VTE are excluded

5.41 The submission claimed that the concerns about the safety of oral versus topical estradiol are addressed by excluding women with risk factors for VTE.

5.42 However, the submission conceded that excluding women with risk factors for VTE would not reduce the risk to the same level as with topical estradiol. The submission did not clearly describe how the exclusion of women with risk factors could be carried out in practice. VTE is not the only risk that is increased with oral versus topical estradiol.

Exclusion of women at increased risk of VTE

5.43 The submission stated that the absolute risk of VTE in women aged < 60 with no identified risk factors for VTE is about 1 per 1000 woman years, and the relative risk associated with oral versus topical MHT is 2-3. That is, the submission conceded that even in women with no known risk factors for VTE there is an increased risk of VTE with Bijuva.

5.44 The submission provided inconsistent and insufficiently specific proposals regarding the identification of women at increased risk of VTE. The submission stated that Bijuva may be used in women without risk factors for VTE (including a personal or family history of VTE or elevated body mass index), while also indicating that the absence of

prior VTE and thrombophilia defines the potential population suitable for oral menopausal hormone therapy.

5.45 Data from the Australian Institute of Health and Welfare indicate that 36% of Australian women aged 45-64 are obese (BMI > 30 kg/m^2) and over half have a BMI > 25 kg/m^2.[8] A claim of non-inferior safety is not reasonable if elevated BMI is included as a risk factor for VTE, as one third to one half of the population is excluded.

5.46 The absence of "previous VTE and thrombophilias" does not exclude either. Some patients with deep vein thrombosis are asymptomatic and many have mild and non-specific symptoms, and not all patients with symptomatic VTE are diagnosed.[9]

5.47 The submission noted that consensus guidelines suggest that in the absence of risk factors for VTE the absolute risk of VTE with oral MHT is about 3/1000 woman years, and this may be acceptable to women who cannot tolerate topical MHT or prefer oral MHT (Davis, 2023b; Table ES.2, p iv of the submission). This is reasonable.

5.48 The submission referred to the results of the REPLENISH trial, from which women at increased risk of VTE were excluded, as showing that Bijuva would be as safe as topical estradiol in the proposed eligible population. Women were excluded from REPLENISH if their BMI was > 34 kg/m^2, if they were smokers or users of electronic cigarettes, if they had recently used a CYP3A4 inhibitor (these increase estradiol exposure) or if they had a thromboembolic disorder or other vascular disease, clotting, or malabsorption disorder.

5.49 Despite these exclusions, there was one VTE event in REPLENISH, a patient treated with estradiol and progesterone with a family but not personal history of deep vein thrombosis (Archer, 2019, p735). Since these exclusions are more extensive than those proposed for the PBS-eligible population and adherence to exclusion criteria is much more consistent in clinical trials than in routine practice.

5.50 The pre-PBAC response stated that in routine clinical practice prescribing of MHT is inherently risk-stratified, with prescribers assessing VTE risk factors, including prior history, obesity, and comorbidities, prior to initiation.

Conditions other than VTE affecting the relative safety of topical and oral estradiol

5.51 The PBAC's previously expressed view that topical MHT preparations were not comparable with oral preparations because of the greater risks of adverse events with oral estrogen was not related only to VTE risk: "oral estrogen carries a higher risk of venous thromboembolism (VTE) than transdermal estrogen, and [...] oral estrogen is contraindicated in patients with risk factors for VTE or cardiovascular disease,

[8] aihw-phe-251-overweight-obesity-data-tables-2024_2 accessed 31 March 2026.

[9] Huisman M, Bauer KA. Clinical presentation and diagnosis of the nonpregnant adult with suspected deep vein thrombosis of the lower extremity. In: Connors RF, ed, UpToDate, accessed 8 June 2026.

elevated triglycerides, liver disease, or gallbladder disease" (Paragraph 5.2, estradiol with progesterone PSD, November 2025 PBAC Meeting).

5.52 Other conditions are included in consensus guidelines and in the treatment algorithm provided in the submission as reasons to prefer topical to oral estrogens on the grounds of safety: variable blood pressure control; migraine; use of CYP3A4 inducers (Davis, 2023a; British Menopause Society, 2024c; Figure 3-1, p32 of the submission).

5.53 Although the increases in the risk of these conditions when oral rather than topical estradiol is used are small or moderate, some of the conditions are common, so that small increases in risk may be considered cumulatively important.

Clinical claim

5.54 The submission described Bijuva as non-inferior in terms of effectiveness in treating VMS compared to oral estradiol and progesterone given concomitantly and compared to topical estradiol with co-packaged oral progesterone. This claim was adequately supported.

5.55 The submission described Bijuva as superior in terms of safety compared to oral estradiol and progesterone given concomitantly. The PBAC Secretariat considered that this claim was uncertain as it was based on a link between unsupported claims of poor compliance with the progesterone component of oral estradiol and progesterone given concomitantly and a possible higher risk of endometrial carcinoma with sequential combined MHT.

5.56 The submission described Bijuva as at least non-inferior in safety to topical estradiol with co-packaged oral progesterone. This included two claims. The first was that Bijuva was non-inferior to Estrogel Pro in relation to VTE risk, provided women at increased risk of VTE are excluded. The PBAC Secretariat considered that this claim was uncertain, because oral estradiol increases the risk of VTE relative to topical estradiol in women who have no risk factors for VTE, and the submission did not provide evidence that an assessment of VTE risk that would be feasible in routine care would avoid inadvertent use of Bijuva in women with risk factors for VTE. The second claim was that Bijuva may be superior to Estrogel Pro in relation to endometrial carcinoma risk. The PBAC Secretariat considered that this claim was not adequately supported, for the same reason as the equivalent claim in relation to oral estradiol and progesterone taken concomitantly.

5.57 The PBAC considered that the claim of non-inferior efficacy was reasonable.

5.58 The PBAC considered that the claim of non-inferior safety for the risk of VTE was not adequately supported.

5.59 The PBAC advised that a claim of superior safety and at least non-inferior safety compared to oral estradiol and progesterone separately and Estrogel Pro respectively, regarding endometrial cancer was not adequately supported. The PBAC considered that a claim of non-inferior safety was reasonable.

Economic analysis

5.60 The submission did not present an economic analysis.

5.61 The submission presented a derivation of a proposed price for Bijuva based on IQVIA data showing how patients switched to the product from March 2025 onwards - following the introduction of Estrogel Pro on to the PBS. The submission proposed an AEMP of $[redacted], calculated using a weighted average price based on substitution for both the combination product (Estrogel Pro) and the individual components. The submission stated that the proposed price was a [redacted]% discount of the previously proposed AEMP of $[redacted].

5.62 The submission presented the data in Table 4 to support the proposed price.

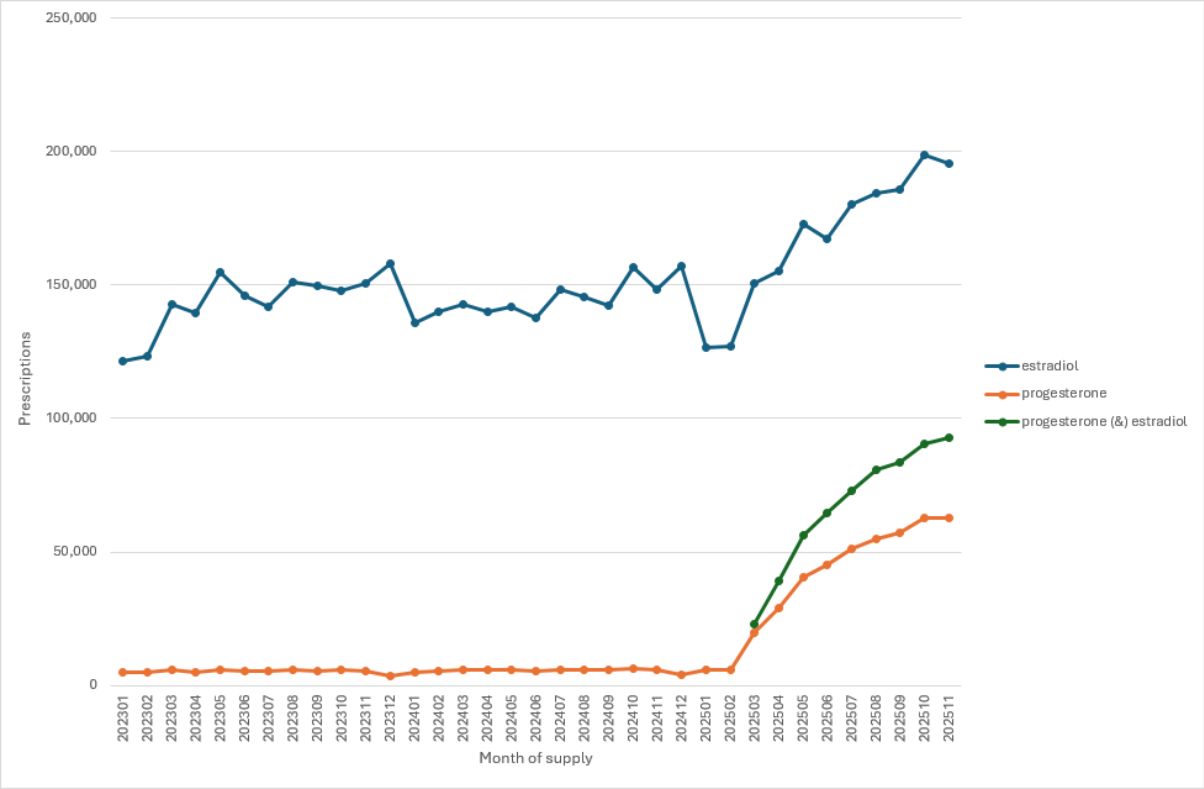
Table 4: March- May 2025 Switch in Units

Category	Units	% proportion to total	Split	
Topical sex hormone	[redacted]	[redacted]%		rebased
Gel	[redacted]	[redacted]%	[redacted]%	[redacted]%
Patches	[redacted]	[redacted]%		
Combined Orals - All	[redacted]	[redacted]%	[redacted]%	[redacted]%
Other	[redacted]	[redacted]%		
Total	[redacted]			

Source: Table 4.1, p 45 of the submission.

5.63 An analysis by the DUSC Secretariat of the utilisation data for oral and topical oestrogen and progestogen products supported the proposal in the submission that there is more likely to be substitution to the combination product (see Figure 1).

Figure 1: Utilisation of estradiol, progesterone and progesterone & estradiol combination from 1 Jan 2023 to the end of November 2025



Source: Analysis of PBS Services data, December 2025, Drug Utilisation Section Department of Health.

5.64 The submission calculated the weighted price as shown in Table 5.

Table 5: Bijuva Price Derivation

Product		AEMP	Doses (days)	cost per day	Bijuva days coverage equivalence	Total cost per 28 days	Weighting	Weighted average price Bijuva
Orals	Progesterone Capsule 100 mg	$[redacted]	30	$[redacted]	25	$[redacted]		
	estradiol valerate 1 mg	$[redacted]	56	$[redacted]	28	$[redacted]		
	Total					$[redacted]	[redacted]%	
Estrogel Pro 64 doses		$[redacted]	32	$[redacted]	28	$[redacted]	[redacted]%	
								$[redacted] (AEMP) $[redacted] (DPMQ, 30 days)

Source: Table 4.2, p 45 of the submission.

Drug cost/patient/ year

5.65 The estimated costs per patient per year of Bijuva, Estrogel Pro, estradiol 1mg and progesterone 100mg based on the proposed DPMQ for Bijuva and the published DPMQs for the comparator products are shown in Table 6.

Table 6: Estimated cost / patient /year

	DPMQ, days	Cost /day	Cost per year (Cost per day x 365.25)
Bijuva	$[redacted], 28	$[redacted]	$[redacted]
Bijuva, revised previous submission	$[redacted], 28	$[redacted]	$[redacted]
Estrogel Pro	$[redacted], 32	$[redacted]	$[redacted]
Estradiol 1mg	$[redacted], 56	$[redacted]	$[redacted]
Progesterone 100mg	$[redacted], 30	$[redacted]	$[redacted] †
Combination estradiol + progesterone			$[redacted]

Source: calculated during the evaluation as shown.† calculated annual cost based on 25 days of progesterone out of a standard 28 day cycle.

Estimated PBS usage & financial implications

5.66 The submissions presented an updated set of estimates of financial impact and cost to the PBS, using an abridged epidemiological/market share approach. The key inputs used in the analysis are shown in Table 7.

Table 7: Key inputs for financial estimates

Parameter	Value	Source	Comment
Market:			
Existing Market: Estrogel Pro projected for 2025, estradiol valerate tablets 1mg and progesterone capsules 100g	1,085,957 Scripts in 2025	Medicare Statistics, PBS items: 14721T 14720R 1663M 13872D 14730G 14733K	*Appropriate*
% Growth Rate	Estrogel Pro, Estradiol 30 day, Estradiol 60 day Yr 1: 9.43%, 5%, 100% Yr 2: 8.62%, 5%, 50% Yr 3: 4.76%, 5%, 25% Yr 4: 4.55%, 5%, 10% Yr 5: 5.80%, 5%, 10% Yr 6: not estimated	Linear estimate based on recreating Estrogel Pro estimates from ranges given in the PSD, linear extrapolation. For estradiol – based on PBS services data 2007-205, linear extrapolation	*Appropriate*
% Treatment Uptake Rate	From Estrogel Pro, oral presentations: Yr 1: [redacted]%, [redacted]% Yr 2: [redacted]%, [redacted]% Yr 3: [redacted]%, [redacted]% Yr 4: [redacted]%, [redacted]% Yr 5: [redacted]%, [redacted]% Yr 6: [redacted]%, [redacted]%	Nov 2025 submission, sponsor assumption	*Unchanged from November 2025 for Estrogel Pro; uptakes from oral products not consistent with weighting used in Table 5.*
Script Equivalence	1 Estrogel Pro :1.14 Bijuva scripts 1 estradiol 1mg : 2 Bijuva scripts 1 progesterone capsule 100mg : 1.2 Bijuva scripts	Cells Worksheet 3a, Financial Workbook.	*States dose equivalence adjusted according to PBAC PSD Nov 2025*
MBS Impacts	None		*Appropriate*

Source: Tables 5.1, 5.2, 5.3, pp47, 50, and Sheet 2e, Attachment 3 of the submission.

5.67 The estimated use and financial impact to the PBS is shown in Table 8.

Table 8: Estimated use and financial implications

	Year 1 (2026)	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use – scripts displaced						
Estrogel pro (30 day)	[redacted][1]	[redacted][2]	[redacted][3]	[redacted][4]	[redacted][5]	[redacted][6]
Estrogel pro (60 day)	[redacted][7]	[redacted][8]	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][9]
Estradiol (30 day)	[redacted][10]	[redacted][8]	[redacted][10]	[redacted][10]	[redacted][1]	[redacted][1]
Estradiol (60 day)	[redacted][11]	[redacted][11]	[redacted][7]	[redacted][8]	[redacted][8]	[redacted][8]
Progesterone (30 day)	[redacted][8]	[redacted][8]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][9]
Progesterone (60 day)	—	[redacted][7]	[redacted][8]	[redacted][8]	[redacted][1]	[redacted][2]
TOTAL	[redacted][3]	[redacted][12]	[redacted][13]	[redacted][13]	[redacted][14]	[redacted][14]
BIJUVA scripts						
Bijuva 30 day	[redacted][9]	[redacted][4]	[redacted][5]	[redacted][13]	[redacted][13]	[redacted][13]
Bijuva 60 day	[redacted][8]	[redacted][1]	[redacted][9]	[redacted][3]	[redacted][15]	[redacted][5]
TOTAL	[redacted][3]	[redacted][5]	[redacted][13]	[redacted][13]	[redacted][14]	[redacted][14]
Estimated financial implications of BIJUVA (DPMQ)						
Cost to PBS/RPBS less copayments	$[redacted][16]	$[redacted][16]	$[redacted][16]	$[redacted][16]	$[redacted][16]	$[redacted][16]
Estimated financial implications for Estrogel Pro, estradiol and progesterone						
Cost to PBS/RPBS less copayments	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]
Net financial implications						
Net cost to PBS/RPBS	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]
Previous submission November 2025						
Total prescription numbers	[redacted][1]	[redacted][9]	[redacted][4]	[redacted][5]	[redacted][13]	[redacted][13]
Estimated financial implications of Bijuva	$[redacted][16]	$[redacted][16]	$[redacted][16]	$[redacted][16]	$[redacted][16]	$[redacted][16]
Cost to the PBS/RPBS less copayments	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]
Net cost to PBS/RPBS	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]

Source: Tables 5.4, 5.5, 5.7. pp 51, 52, 53 of the submissions and Table 11, Ratified PBAC Minutes estradiol and progesterone , November 2025.

The redacted values correspond to the following ranges:

[1] *20,000 to < 30,000*
[2] *30,000 to < 40,000*
[3] *50,000 to < 60,000*
[4] *60,000 to < 70,000*
[5] *80,000 to < 90,000*
[6] *100,000 to < 200,000*
[7] *5,000 to < 10,000*
[8] *10,000 to < 20,000*
[9] *40,000 to < 50,000*
[10] *5,000 to < 10,000*
[11] *500 to < 5,000*
[12] *90,000 to < 100,000*
[13] *100,000 to < 200,000*
[14] *200,000 to < 300,000*
[15] *70,000 to < 80,000*
[16] *0 to < $10 million*
[17] *net cost saving*

5.68 The total cost to the PBS/RPBS of listing Bijuva was estimated to be $0 to < $10 million in Year 6, and a total of $30 million to < $40 million in the first 6 years of listing. The submissions estimated that overall there would be a net saving to the PBS with the reduction in use of Estrogel Pro and the individual components.

5.69 If the displacement of the products containing the oral components is greater than predicted the cost will be higher.

5.70 The submissions did not present any sensitivity analyses on the financial estimates. The estimate of the total number of prescriptions in the submissions was approximately double that in the November 2025 submission. This was due to the inclusion of uptake from the oral products. The total cost to the PBS remained about the same compared to the November 2025 PBAC consideration. This was due to the price decrease and substitution of the oral products.

Quality Use of Medicines

5.71 The submission did not present any information specifically about the quality use of medicines with respect to BIJUVA. The submission claimed that women may prefer single, daily, continuously taken capsule, with a simple administration schedule that may enhance compliance/adherence to therapy.

6 PBAC outcome

6.1 The PBAC provided further consideration of its November 2025 recommendation to list oral estradiol with progesterone (Bijuva) as a General Schedule unrestricted benefit listing, and corresponding General Schedule restricted benefit listings for 60-day maximum dispensed quantity.

6.2 The PBAC recalled its November 2025 recommendation to list Bijuva on a cost minimisation basis against estradiol valerate 1 mg tablet (28 days) and progesterone 100 mg capsule (25 days out of a 28-day cycle), and that at the time it had considered that there was insufficient evidence provided to justify a price premium for Bijuva.

6.3 The PBAC noted the claim that Bijuva would have non-inferior safety regarding the risk of VTE compared to Estrogel Pro (co-packed estradiol transdermal gel and oral progesterone), when restricted to women who do not have risk factors for VTE development. The PBAC noted that no changes to the PBS listing were proposed. The PBAC noted that the pre-PBAC response argued that consideration of risk factors for VTE forms part of the routine clinical assessment when deciding on the most appropriate form of MHT to prescribe for an individual. The PBAC considered that the risk of VTE associated with Bijuva may be acceptable to women without risk factors for VTE who cannot tolerate topical MHT or where topical MHT is not suitable. The PBAC advised that Estrogel Pro was an appropriate comparator in this population. However, the PBAC advised that overall, a claim non-inferior safety for the risk of VTE compared to Estrogel Pro across the whole eligible population (women who required MHT) was not supported.

6.4 The PBAC noted that the claim of superior safety and at least non-inferior safety for Bijuva for the risk of endometrial hyperplasia compared to oral estradiol and progesterone prescribed separately and Estrogel Pro was made on the basis that compliance with the progesterone component will be lower when given separately,

resulting in a higher risk of endometrial carcinoma. The PBAC advised that this claim was not adequately supported. The PBAC advised that a claim of non-inferior safety for the risk of endometrial hyperplasia would be reasonable.

6.5 The PBAC recalled the consumer comments from its November 2025 consideration, which included comments from health care professionals that the single-dose, oral form may improve adherence and therefore reduce risk of endometrial hyperplasia, carcinoma and unscheduled bleeding, and may reduce the risk of individuals adjusting the estrogen dose without medical supervision. One comment stated that improved ease of administration is important for individuals with limited health literacy. Sexual Health Victoria and WellFemme Telehealth Menopause Clinic had also commented that estradiol with progesterone as an oral preparation is an option for individuals who have impaired absorption of transdermal estrogen, and the combined preparation can assist with adherence, leading to better symptom management and reduce the risk of accidental unopposed estrogen exposure if progesterone is not taken at the same time as the estrogen. Sexual Health Victoria stated that, as an oral preparation, it would not be suitable for some individuals, such as those with a high risk of VTE or cardiovascular events. It commented that the listing of MP on the PBS has decreased the financial barrier to this medication, however currently individuals who want to use MP but do not or cannot use a transdermal estrogen are unable to access this medication in a combined preparation, limiting access and choice.

6.6 The PBAC reiterated its previous advice that there is a need to maintain a diverse range of MHT options on the PBS. The PBAC noted that there is currently no oral fixed dose combination product containing estradiol and progesterone (or a progestogen) for continuous MHT listed on the PBS. Overall, the PBAC was satisfied that inclusion of Bijuva, as a combined oral capsule, would offer additional options to women requiring MHT and facilitate individualised treatment choices, and that it may offer a meaningful difference to some patients compared to MHT options currently PBS-listed. The PBAC reaffirmed its November 2025 listing recommendation and noted that no changes were required.

6.7 The PBAC noted that the requested price for Bijuva was a 15.6% reduction compared to the price considered in November 2025. The PBAC noted that the price requested for Bijuva was at a modest monthly premium over the individual components, but advised that listing at the requested price was acceptable, given the need to maintain diverse treatment options for women requiring MHT.

6.8 PBAC noted that financial estimates model accounted for substitution of both the oral components and Estrogel Pro. The PBAC noted that there was inconsistency in the treatment uptake assumptions compared to the weighting used to calculate the price of Bijuva. The PBAC advised that overall, the assumptions underlying the financial estimates were reasonable.

6.9 The PBAC noted that the total cost to the PBS/RPBS of listing Bijuva was estimated to be $10 million to < $20 million in Year 6, and a total of $30 million to < $40 million in the first 6 years of listing. However, overall, there would be a net saving to the PBS

with the reduction in use of Estrogel Pro and the individual components. The PBAC noted that if displacement of the oral components was higher than anticipated then the total cost savings may not be fully realised. The PBAC advised that the financial estimates were reasonable.

6.10 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Add new item:

30-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ESTRADIOL + PROGESTERONE					
estradiol 1 mg + progesterone 100 mg capsule, 28	NEW MP NP	1	28	5	Bijuva
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒unrestricted benefit				

60-day listing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ESTRADIOL + PROGESTERONE					
estradiol 1 mg + progesterone 100 mg capsule, 28	NEW MP NP	2	56	5	Bijuva
	Category / Program: ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒ Restricted benefit				
	Indication: The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.				

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.