

**5.25 DORZOLAMIDE WITH TIMOLOL,
Eye drops containing dorzolamide 20 mg (as
hydrochloride) with timolol 5 mg (as maleate) per
mL, 5 mL,
Vizo-PF Dorzolatim[®],
AFT Pharmaceuticals (Au) Pty Ltd**

1 Purpose of Submission

- 1.1 The Committee Secretariat submission requested a Restricted Benefit listing of a new ophthalmic eye drops solution in a preservative-free (PF) multi-dose bottle, Vizo-PF Dorzolatim[®], under the same circumstances as the currently listed brands of dorzolamide + timolol eye drops (Cosopt[®] and Cosdor[®]).

2 Background

Registration status

- 2.1 Vizo-PF Dorzolatim was Therapeutic Goods Administration (TGA) registered on 22 September 2021 for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma when concomitant therapy is appropriate.
- 2.2 The TGA approval letter stated bioequivalence of Vizo-PF Dorzolatim to Cosopt 5 mL bottle eye drops and Cosopt PF single dose eye drops.

Previous PBAC consideration

- 2.3 The Pharmaceutical Benefits Advisory Committee (PBAC) has not previously considered a submission for Vizo-PF Dorzolatim.

For more detail on PBAC's view, see section 6 PBAC outcome.

3 Requested listing

- 3.1 The submission requested Vizo-PF Dorzolatim to be 'a'-flagged against Cosopt. The PBAC was asked to advise under Section 101(4AACD) of the *National Health Act 1953* whether Vizo-PF Dorzolatim should be treated as equivalent to Cosopt and Cosdor for the purposes of substitution (i.e. 'a'-flagged).
- 3.2 The submission requested a new Pharmaceutical Benefits Scheme (PBS) item code with the same restriction wording as the current PBS listing for Cosopt (8567X and 5542Q). Creating new PBS item codes would not be necessary because Vizo-PF

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Dorzololamim could be added to the existing PBS item codes (8567X and 5542Q) instead, if recommended.

Add new trade product pack as follows:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
DORZOLAMIDE + TIMOLOL dorzolamide 2% + timolol 0.5% eye drops, 5 mL	8567X	1	1	5	Cosdor Cosopt Vizo-PF Dorzololamim

Restriction Summary / Treatment of Concept:

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input checked="" type="checkbox"/> Restricted benefit
Indication: Elevated intra-ocular pressure
Clinical criteria: The condition must have been inadequately controlled with monotherapy
AND
Clinical criteria: Patient must have open-angle glaucoma; or Patient must have ocular hypertension

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
DORZOLAMIDE + TIMOLOL dorzolamide 2% + timolol 0.5% eye drops, 5 mL	5542Q	1	1	5	Cosdor Cosopt Vizo-PF Dorzololamim

Restriction Summary / Treatment of Concept:

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input checked="" type="checkbox"/> Restricted benefit
Indication: Elevated intra-ocular pressure
Clinical criteria: The condition must have been inadequately controlled with monotherapy
AND
Clinical criteria: Patient must have open-angle glaucoma; or Patient must have ocular hypertension
Administrative Advice: For prescribing in accordance with Optometry Board of Australia guidelines.

For more detail on PBAC's view, see section 6 PBAC outcome.

4 Comparator

4.1 The submission nominated Cosopt® as the main comparator. This was appropriate.

For more detail on PBAC's view, see section 6 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted that this item received no consumer comment.

Pricing consideration

5.3 The sponsor proposed an approved ex-manufacturer price (AEMP) of \$9.85 and dispensed price for maximum quantity (DPMQ) of \$22.67 for Vizo-PF Dorzololamim, which is equivalent to Cosopt and Cosdor.

Estimated PBS utilisation and financial implications

5.4 The submission estimated there to be no financial implications to the PBS/RPBS from the listing of Vizo-PF Dorzololamim over six years.

5.5 The submission did not anticipate an increased market size or growth as a result of the PBS listing of Vizo-PF Dorzololamim.

5.6 The submission estimated that Vizo-PF Dorzololamim will substitute for 5% market share in the first year of listing (5,000 to < 10,000 prescriptions), increasing to approximately 25% by Year 6 (30,000 to < 40,000 prescriptions).

5.7 As a Committee Secretariat submission, the financial estimates were not independently evaluated.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

6.1 The PBAC recommended the listing of a new ophthalmic eye drops solution in a preservative-free (PF) multi-dose bottle, Vizo-PF Dorzololamim, under the same circumstances as the currently listed brands of dorzolamide + timolol eye drops (Cosopt and Cosdor), for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma when concomitant therapy is appropriate.

6.2 The PBAC noted Cosopt as the main comparator.

- 6.3 The PBAC noted that the TGA stated that Vizo-PF Dorzolotim is bioequivalent to both the preservative-containing and PF forms of Cosopt. The PBAC advised, under section 101(4AACD) of the *National Health Act 1953*, that the Vizo-PF Dorzolotim, Cosopt and Cosdor brands of dorzolamide + timolol eye drops should be considered equivalent for the purposes of substitution (i.e. ‘a’-flagged in the Schedule).
- 6.4 The PBAC noted that the submission estimated no financial implications to the PBS/RPBS from the listing of Vizo-PF Dorzolotim over six years.
- 6.5 The PBAC advised that because Vizo-PF Dorzolotim is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Cosopt and Cosdor, or not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.6 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new trade product pack (Vizo-PF Dorzolotim) to the existing listings for Cosopt and Cosdor as follows:
- 7.2 Add equivalence indicators to the trade products ‘Vizo-PF Dorzolotim’, ‘Cosdor’ and ‘Cosopt’ as follows:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
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Restriction Summary / Treatment of Concept:					
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives					
Restriction Level / Method: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Elevated intra-ocular pressure					
Clinical criteria:					
The condition must have been inadequately controlled with monotherapy					
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Clinical criteria:					
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MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands	
DORZOLAMIDE + TIMOLOL dorzolamide 2% + timolol 0.5% eye drops, 5 mL	5542Q	1	1	5	Vizo-PF Dorzolotim ^a Cosdor ^a Cosopt ^a	
Restriction Summary / Treatment of Concept:						
Category / Program: GENERAL – General Schedule (Code GE)						
Prescriber type: <input type="checkbox"/> Dental <input type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Optometrists <input type="checkbox"/> Midwives						
Restriction Level / Method: <input checked="" type="checkbox"/> Restricted benefit						
Indication: Elevated intra-ocular pressure						
Clinical criteria: The condition must have been inadequately controlled with monotherapy						
AND						
Clinical criteria: Patient must have open-angle glaucoma; or Patient must have ocular hypertension						
Administrative Advice: For prescribing in accordance with Optometry Board of Australia guidelines.						

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.