

14.03 (c) BIMATOPROST
300 micrograms per mL, 3 mL
Vizo-PF Bimatoprost®,
AFT Pharmaceuticals Pty Ltd

For improved readability, tradenames for therapies for the treatment of elevated intraocular pressure or open angle glaucoma are used in the public summary document. In some cases, generic names may be used for clarity.

Table 1 presents a summary of agents used in the first line treatment of elevated intraocular pressure or open angle glaucoma, indicating their components, presentation, associated tradenames and pricing.

Table 1: Summary of prostaglandin analogues used to treat elevated intraocular pressure or open angle glaucoma

Components	Presentation	Tradenname	DPMQ
Bimatoprost PF (agent)	3 mL multi-dose bottle	Vizo-PF Bimatoprost®	NA
Bimatoprost PF(comparator)	30 x 0.4 mL unit doses	Lumigan PF®	\$32.40
Other PBS-listed prostaglandin analogues			
Bimatoprost	3 mL multi-dose bottle	F2 formulary	\$36.40
Latanoprost	2.5 mL multi-dose bottle	F2 formulary	\$17.31
Travoprost	2.5 mL multi-dose bottle	Travatan®	\$36.84
Tafluprost	30 x 0.3 mL unit doses	Saflutan®	\$34.11

DPMQ = Dispensed Price for Maximum Quantity; PF = preservative-free

1 Purpose of Application

1.1 The minor submission requested a General Schedule unrestricted listing for bimatoprost 300 microgram per mL eye drops (Vizo-PF Bimatoprost®) in a preservative-free multi-dose bottle for the reduction of elevated intraocular pressure, or open angle glaucoma, as first line therapy or monotherapy or as adjunctive therapy to topical beta-blockers.

2 Background

Registration status

2.1 Vizo-PF Bimatoprost was TGA registered on 17 January 2020 for the reduction of elevated intraocular pressure, or open angle glaucoma, as first line therapy or monotherapy or as adjunctive therapy to topical beta-blockers. This is the same TGA indication as that for the proposed comparator (Lumigan PF®, paragraph 4.1).

Previous PBAC consideration

2.2 The PBAC has not previously considered Vizo-PF Bimatoprost.

3 Requested listing

- 3.1 The submission requested Vizo-PF Bimatoprost be made available through the PBS under the same circumstances as the currently PBS-listed proposed comparator (Lumigan PF).
- 3.2 Secretariat suggested additions are in italics and deletions are in strikethrough.

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Name and Manufacturer	
BIMATOPROST Bimatoprost 300 microgram/mL, 3mL Eye Drops	<i>NEW</i>	1	1	5	Vizo-PF Bimatoprost	AFT Pharmaceuticals (AU) Pty Ltd

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Optometrists
Restriction Type: <input checked="" type="checkbox"/> Unrestricted benefit
Administrative note: <i>Pharmaceutical benefits that have the form bimatoprost preservative-free single dose ampoules and pharmaceutical benefits that have the form bimatoprost preservative-free multi-dose bottle are equivalent for the purposes of substitution.</i>

- 3.3 Vizo-PF Bimatoprost is considered bioequivalent to the PBS-listed Lumigan PF product by the TGA in the TGA Delegate’s approval letter.
- For more detail on PBAC’s view, see section 6 PBAC outcome.*

4 Comparator

- 4.1 The minor submission nominated bimatoprost preservative-free single dose ampoules (300 microgram per mL) eye drops (Lumigan PF) as the main comparator.
- 4.2 If treatment with Vizo-PF Bimatoprost is substantially more costly than any of the alternative therapies (other prostaglandin analogues), the PBAC could only recommend listing Vizo-PF Bimatoprost if it is satisfied that it provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapies (National Health Act 1953, Section 101(3B)).
- 4.3 The submission did not provide a rationale or justification for nominating Lumigan PF as the main comparator. The submission assumed that Lumigan PF is the appropriate comparator because Vizo-PF Bimatoprost is considered bioequivalent to the PBS-listed Lumigan PF by the TGA. However, it is possible that several other prostaglandin analogues used in the first line treatment of elevated intraocular pressure or open angle glaucoma may be relevant comparators, namely PBS-listed agents provided in multi-dose bottles containing preservative: bimatoprost (F2 formulary), latanoprost (F2 formulary), and travoprost (Travatan®); or a preservative-free agent provided in single dose ampoules, tafluprost (Saflutan®). Both bimatoprost (Lumigan®) and

travoprost were approved for PBS listing on a cost minimisation basis against latanoprost in 2002. Tafluprost (preservative-free) was approved for PBS listing from a cost analysis against latanoprost (13.65% lower price) at the March 2012 meeting. Lumigan PF was approved for PBS listing from a minor submission at the November 2013 meeting.

- 4.4 The PBAC noted that latanoprost (F2 formulary) has become the least costly comparator (Table 1) following a statutory price reduction on 1 August 2012 with the first new bioequivalent brand becoming available.

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 as it was a committee secretariat submission.

Consumer comments

- 5.2 The PBAC noted that no consumer comments were received for this item.

Clinical claim

- 5.3 The TGA considered that Vizo-PF Bimatoprost is bioequivalent to Lumigan PF. Vizo-PF Bimatoprost and Lumigan PF are both preservative-free, with the only difference being Vizo-PF Bimatoprost comes in a multi-dose bottle compared to single dose ampoules for Lumigan PF.
- 5.4 The submission claimed Vizo-PF Bimatoprost is non-inferior and equivalent to eye drops containing bimatoprost with preservative (Lumigan) in its ability to reduce intraocular pressure, with a similar safety profile. The submission did not define Lumigan (with preservative) as a relevant comparator, nor did it present evidence to support this claim, but provided a reference to a published study.¹
- 5.5 The sponsor considered that Vizo-PF Bimatoprost would provide an alternative to the currently PBS-listed Lumigan PF for the treatment of glaucoma and intraocular pressure due to its convenient multi-dose delivery method that may help improve patient compliance and minimise drug wastage. The sponsor considered it is also an effective treatment option for patients who are intolerant to preservatives or have an

¹ Day DG, Walters TR, Schwartz GF, Mundorf TK, Liu C, Schiffman RM, Bejanian M. Bimatoprost 0.03% preservative-free ophthalmic solution versus bimatoprost 0.03% ophthalmic solution (Lumigan) for glaucoma or ocular hypertension: a 12-week, randomised, double-masked trial. *Br J Ophthalmol.* 2013 97(8):989-93.

inadequate response to other treatments. The submission did not present evidence to support this claim, but provided a reference to a published review.²

- 5.6 The PBAC considered that Vizo-PF Bimatoprost has non-inferior comparative effectiveness and safety compared with the nominated comparator, Lumigan PF.

Economic analysis

- 5.7 The minor submission presented a cost-minimisation analysis of Vizo-PF Bimatoprost compared with Lumigan PF. The equi-effective doses were estimated as Vizo-PF Bimatoprost one drop per eye per day and Lumigan PF one drop per eye (one ampoule) per day.

- 5.8 The proposed ex-manufacturer price (AEMP) for one 3 mL bottle of Vizo-PF Bimatoprost is \$ [REDACTED] (cost per treatment per pack \$ [REDACTED] x 28 (total number of treatment both eyes per pack)). The proposed price of Vizo-PF Bimatoprost, as requested by the Sponsor, and the price of the comparator are presented in Table 2.

Table 2: Results of the cost minimisation analysis as requested by the Sponsor

		Lumigan PF	Vizo-PF Bimatoprost	Source/calculation
A	Ex-manufacturer price	\$19.46	\$ [REDACTED]	Lumigan PF = ex-manufacturer price Vizo-PF Bimatoprost = C * B
B	Duration of therapy per pack	30 days	28 days	Lumigan PF = 30 ampoules per pack Vizo-PF Bimatoprost = contents discarded after 28 days
C	Cost per treatment per day (ex-manufacturer)	\$0.6487	\$ [REDACTED]	Lumigan PF = A / B Vizo-PF Bimatoprost = assumed equal to or less than Lumigan PF

- 5.9 The submission did not present an economic evaluation of Vizo-PF Bimatoprost compared with the cheapest potentially relevant comparator, latanoprost (multi-dose bottle containing preservative, AEMP \$5.42 for 28 days). The PBAC considered that the cost minimisation should be performed against the lowest priced alternative agent (latanoprost) (Table 3) using a 1:1 dosing relativity.

² Baudouin C, Labbé A, Liang H, Pauly A, Brignole-Baudouin F, 2010. Preservatives in eye drops: the good, the bad and the ugly. Prog Retin Eye Res; 29(4):312-334.

Table 3: Results of the cost minimisation analysis against the lowest priced alternative agent (latanoprost)

		Latanoprost	Vizo-PF Bimatoprost	Source/calculation
A	Ex-manufacturer price	\$5.42	\$5.42	Latanoprost = ex-manufacturer price Vizo-PF Bimatoprost = C * B
B	Duration of therapy per pack	28 days	28 days	Latanoprost = contents discarded after 28 days Vizo-PF Bimatoprost = contents discarded after 28 days
C	Cost per treatment per day (ex-manufacturer)	\$0.1936	\$0.1936	Latanoprost = A / B Vizo-PF Bimatoprost = assumed equal to latanoprost

Drug cost/patient/year: \$ [REDACTED]

5.10 The estimated drug cost/patient/year would be \$ [REDACTED], based on 13.04 scripts/patient/year at the sponsor’s requested DPMQ of \$ [REDACTED]. Using the lowest priced alternative agent’s DPMQ of \$17.31, the estimated drug cost/patient/year would be \$225.72 for 13.04 scripts/patient/year.

Estimated PBS usage & financial implications

5.11 The minor submission used a market share approach to estimate the uptake and financial implications of Vizo-PF Bimatoprost. The submission assumed that Vizo-PF Bimatoprost would substitute for 5% of Lumigan PF use within the first year of listing, rising to 50% in the sixth year. The submission predicted growth within the Lumigan PF market of 6% in 2019 decreasing to 1% in 2024 for 10046R, and 11% in 2019 decreasing to 3% in 2024 for 10053D. The submission estimated there to be no net additional cost to the PBS over six years, as the proposed price for Vizo-PF Bimatoprost is marginally below Lumigan PF. The sponsor did not present the results of their financial implications model in the submission and the assumptions used in the model are not clearly documented.

5.12 The minor submission estimated a net saving to the PBS in Year 6 of listing (Table 4), with a total net saving to the PBS over the first 6 years of listing.

Table 4: Estimated use and financial implications of Vizo-PF Bimatoprost to the PBS/RPBS

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use							
Scripts dispensed ^a							
Vizo-PF Bimatoprost scripts							
Estimated financial implications of Vizo-PF Bimatoprost (net cost to PBS/RPBS^b)							
Vizo-PF Bimatoprost		\$	\$	\$	\$	\$	\$
Estimated treatment replaced							
Lumigan PF	10046R	-	-	-	-	-	-
Lumigan PF	10053D	-	-	-	-	-	-
Total		-	-	-	-	-	-
Estimated financial implications of treatment replaced (net cost to PBS/RPBS^b)							
Lumigan PF	10046R	\$	\$	\$	\$	\$	\$
Lumigan PF	10053D	\$	\$	\$	\$	\$	\$
Total		\$	\$	\$	\$	\$	\$
Net financial implications							
Net cost to PBS/RPBS		-\$	-\$	-\$	-\$	-\$	-\$

DPMQ = dispensed price for maximum quantity; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

^a Total Lumigan PF scripts (codes 10046R and 10053D).

^b Costs represent DPMQ minus copayment.

Source: Utilisation-and-cost-model-workbook-release-3_AFT Vizo-PF Bimatoprost 230420.xlsx of the submission.

The redacted table shows that at Year 6, the estimated number of scripts dispensed was 100,000 to < 200,000 and the number of Vizo-PF Bimatoprost scripts was 5,000 to < 70,000 and the net cost to the PBS would be net cost saving."

5.13 The submission did not consider the financial implications of prostaglandin analogues other than Lumigan PF being replaced should Vizo-PF Bimatoprost be PBS-listed. If Vizo-PF Bimatoprost replaces latanoprost at the Lumigan PF price, there will be a net cost to the PBS. The Sponsor stated in their pre-PBAC response (p3) that 'there could be some switching between latanoprost and Vizo-PF Bimatoprost but this is likely to be insignificant since other prostaglandin analogues have already been listed on the PBS for several years and already have a well established market use.' The PBAC considered that, without evidence to support the Sponsor's argument, the possibility of switching between prostaglandin analogues cannot be discounted.

5.14 As a minor submission, the financial estimates have not been 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 form of bimatoprost 300 microgram per mL eye drops (Vizo-PF Bimatoprost) in a preservative-free multi-dose bottle as an unrestricted benefit on a cost minimisation basis against the lowest priced alternative agent (latanoprost).

6.2 Vizo-PF Bimatoprost is considered bioequivalent to the PBS-listed Lumigan PF by the TGA. While the minor submission nominated Lumigan PF as the main comparator, the

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PBAC noted that latanoprost is currently the least costly comparator. On the basis that Vizo-PF Bimatoprost does not provide an improvement in either efficacy or safety over either preserved or non-preserved agents, a cost minimisation including preserved agents is appropriate, using the lowest priced alternative agent.

- 6.3 The PBAC noted there were five safe and efficacious alternative prostaglandin analogues available as treatments for patients, and considered the need for additional treatment options was low.
- 6.4 The PBAC noted that the new multi-dose bottle has the same medicinal product pack description of 'bimatoprost 0.03% eye drops, 3 mL' as the existing products that are not preservative free. Therefore, under ordinary listing circumstances, Vizo-PF Bimatoprost would be added to the existing PBS item codes as a new brand and marked as equivalent ('a-flagged') with these various other brands. However, for patients allergic to preservatives, this would run the risk of permitting pharmacists to inadvertently substitute between preservative and non-preservative products. To avoid this situation, the Secretariat recommended allocating Vizo-PF Bimatoprost its own unique PBS item code so that substitution could occur between Vizo-PF Bimatoprost and Lumigan PF only for the preservative-free products.
- 6.5 The PBAC advised that Vizo-PF Bimatoprost is suitable for prescribing by optometrist practitioners, similar to other bimatoprost products currently listed for this indication.
- 6.6 The PBAC advised that Vizo-PF Bimatoprost is not suitable for prescribing by nurse practitioners.
- 6.7 The PBAC recommended that the Early Supply Rule should not apply to Vizo-PF Bimatoprost as it does not apply to other bimatoprost listings.
- 6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that because Vizo-PF Bimatoprost is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over alternative therapies, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by *the National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for pricing Pathway A were not met.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new non-originator trade product pack of 'Vizo-PF Bimatoprost' MPP to new PBS item code.
- 7.2 Add equivalence indicator (a-flag) to Lumigan PF and Vizo-PF Bimatoprost brands.

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7.3 Add administrative note to Lumigan PF and Vizo-PF Bimatoprost listings that explains that the 2 forms are equivalent for the purposes of substitution.

Medical practitioner listings:

New:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
BIMATOPROST bimatoprost 0.03% eye drops, 3 mL	NEW	1	1	5	^a Vizo-PF Bimatoprost

New:

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit
Administrative advice: Pharmaceutical benefits that have the form bimatoprost eye drops, 30 x 0.4 mL unit doses and pharmaceutical benefits that have the form bimatoprost eye drops, 3 mL that are preservative free, are equivalent for the purposes of substitution.

Existing Lumigan PF listing:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
BIMATOPROST bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	10046R	1	1	5	^a Lumigan PF

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit
Administrative advice: Pharmaceutical benefits that have the form bimatoprost eye drops 30 x 0.4 mL unit doses and pharmaceutical benefits that have the form bimatoprost eye drops 3 mL that are preservative free, are equivalent for the purposes of substitution.

Optometry listings:

New:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
BIMATOPROST Bimatoprost 0.03% eye drops, 3 mL	NEW	1	1	5	^a Vizo-PF Bimatoprost

New:

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Optometrists
Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit
Administrative advice: For prescribing in accordance with Optometry Board of Australia guidelines
Administrative advice:

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Pharmaceutical benefits that have the form bimatoprost eye drops 30 x 0.4 mL unit doses and pharmaceutical benefits that have the form bimatoprost eye drops 3 mL that are preservative free, are equivalent for the purposes of substitution.

Existing Lumigan PF listing:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
BIMATOPROST bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	10053D	1	1	5	^a Lumigan PF

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Optometrists
Restriction type: <input checked="" type="checkbox"/> Unrestricted benefit
Administrative advice: For prescribing in accordance with Optometry Board of Australia guidelines
Administrative advice: Pharmaceutical benefits that have the form bimatoprost eye drops 30 x 0.4 mL unit doses and pharmaceutical benefits that have the form bimatoprost eye drops 3 mL that are preservative free, are equivalent for the purposes of substitution.

Existing bimatoprost 0.03% eye drops, 3 mL listings (PBS item codes 8620Q (medical practitioners and 5551E (optometrists)) are not preservative free and are to remain unchanged.

This restriction 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

AFT appreciates the positive recommendation of Vizo-PF Bimatoprost by PBAC. However, AFT did not agree with approach of PBAC used in evaluating this listing application by comparing the price to Latanoprost and disregarding the current pricing of preservative free bimatoprost (Lumigan PF) which is the only bioequivalent product to Vizo-PF that is currently listed on PBS.