

6.09 ANTI-GLAUCOMA MEDICINES

Various; Optometry Australia

1 Purpose of Application

1.1 The minor submission sought to amend the current PBS listings of anti-glaucoma medicines to remove the requirement for a prescribing optometrist to be working in a shared care model with an ophthalmologist, in line with recent regulatory changes made by the Optometry Board of Australia (OBA).

1.2 Below is the list of anti-glaucoma medicines to which the requested change would be applied.

- Betaxolol (0.25% and 0.5%)
- Bimatoprost (bottle and unit doses)
- Bimatoprost + Timolol (bottle and unit doses)
- Brimonidine (0.15% and 0.2%)
- Brimonidine + Timolol
- Brinzolamide
- Brinzolamide + Timolol
- Dorzolamide
- Dorzolamide + Timolol
- Latanoprost
- Latanoprost + Timolol
- Pilocarpine (1%, 2%, 4%)
- Timolol (0.25%, 0.5%, 1%)
- Travoprost
- Timolol + Travoprost

2 Requested listing

2.1 Currently, the medicines listed in Paragraph 1.2 have the following NOTE in the PBS schedule:

‘For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the *‘Guidelines for Shared Care of Glaucoma Patients’*

2.2 The submission sought the following:

- removal of the ‘Shared Care Model’ note from the medicines listed in 1.2 and;
- removal of the *‘PBS Guidelines for Shared Care of Glaucoma Patients’*, which is the document to which the NOTE refers.

Removal of the above would change the arrangements for optometrists prescribing PBS subsidised anti-glaucoma medicines in line with OBA guidelines.

2.3 An alternative option proposed in the submission was to “stipulate the requirement for optometrist prescribing anti-glaucoma preparations to do so in line with the Board’s guidelines as amended from time to time.”

3 Background

- 3.1 The request had not been considered by PBAC previously.
- 3.2 All optometrists practising in Australia must be registered with the OBA, which is responsible for assuring the competence of registered practitioners and for standards of practice. To prescribe medicines, optometrists must obtain endorsement of their registration by satisfying the Board that they have successfully completed a course of study that qualifies the optometrist to prescribe these medicines.
- 3.3 Optometrists accredited to prescribe under the Health Practitioner Regulation National Law and approved as PBS prescribers have been able to write prescriptions for pharmaceutical benefits since 1 January 2008.
- 3.4 In its April 2011 consideration of medicines to be added to the Optometric Schedule, the PBAC stated that “

“The PBAC noted that the competency of optometrists to prescribe is the responsibility of the states and territories and the Optometrist Board of Australia. The PBAC noted that the medicines requested for optometric listing are currently on the list of medicines authorised to be prescribed by authorised optometrists, for the majority of the states and territories. Therefore the ability of these health care professionals to diagnose the condition for which the medicines are used is implicit within the approval of the list of medicines. The Optometrist Board defines the educational requirements for designation as a prescriber and optometrists must be authorised i.e. not all optometrists have prescribing rights.

The PBAC noted that all the requested medicines can be prescribed as private prescriptions by authorised optometrists in the relevant states and territories. Therefore the issue for the PBAC is Quality Use of Medicine (QUM) and PBS-subsidised access for patients by means of authorised health professionals approved to prescribe in the relevant state and territory jurisdictions, rather than work-force capability issues.”

- 3.5 In December 2014, revised Guidelines were released by the OBA that enable endorsed optometrists to make an initial diagnosis and initiate treatment for chronic glaucoma with Schedule 4 anti-glaucoma medications, provided that a referral for ophthalmological assessment to confirm the diagnosis and advice on ongoing management is provided to the patient within four months.
- 3.6 The submission stated that “an agreement (between the Optometry Board of Australia, the Royal Australian and New Zealand College of Ophthalmologists and the Australian Society of Ophthalmologists) was reached out of court for modifications to the Guidelines acknowledged as acceptable by all parties.” Documentation was provided to substantiate that an agreement had been reached between the three parties (the Optometry Board of Australia, the Royal Australian and New Zealand College of Ophthalmologists and the Australian Society of Ophthalmologists), and that the current guidelines reflect that agreement.

Current 'PBS Guidelines for Shared Care of Glaucoma Patients'

3.7 The anti-glaucoma medications listed in paragraph 1.2 can currently be prescribed under the PBS in appropriate circumstances by ophthalmologists or by optometrists working under specified co-management arrangements with an ophthalmologist. The following table summarises the current PBS guidelines for shared care of glaucoma patients.

Summary of Guidelines for Shared Care of Glaucoma Patients

	Guidelines
Initial Referral to Ophthalmologist	<p>An authorised optometrist who makes a provisional diagnosis of glaucoma is to refer the patient to an ophthalmologist for confirmation of the diagnosis and the development of a management plan.</p> <p>Where clinically important delays are expected before the patient's first review by an ophthalmologist, the optometrist should seek interim advice on the patient's management from the ophthalmologist by telephone (or alternate means).</p> <p>The patient's consent is to be obtained by the ophthalmologist and optometrist for all aspects of the management plan, including the sharing of care between the two practitioners, and the communication of clinical information to the patient's nominated general practitioner.</p> <p>Once the diagnosis of glaucoma is confirmed by the ophthalmologist and a treatment plan is in place for the patient, the optometrist can perform ongoing reviews to monitor the patient and prescribe topical drugs under the PBS providing that:</p> <ul style="list-style-type: none"> • Periodic review demonstrates the treatment to be effective, and • Changes to management are only initiated following consultation between treating practitioners. <p>Ophthalmologists must be available for consultation by the treating optometrist and for consultation by the patient where that consultation has been recommended or requested by the optometrist.</p>
Beta Blockers	<p>Patients being considered for anti-glaucoma therapy with a beta blocking agent should be assessed for any potential cardiovascular or respiratory risk by a medical practitioner (often the patient's general practitioner), prior to initiating therapy. This assessment should be repeated if a change in dose of the beta blocker is proposed.</p>
Patient Management Plan	<p>The management plan must be in writing and specify the following:</p> <ol style="list-style-type: none"> 1. All the agreed components of treatment including any drug therapy; 2. Target pressures and action to be taken if these are not achieved within a specified time frame; 3. An agreed approach to monitoring visual fields and optic disc imaging and action to be taken following changes in visual fields; 4. Triggers for referral for more immediate ophthalmological and general practitioner review; 5. Likely side effects from agreed treatment and the action to be taken to address these; 6. An agreed schedule for patient review by both practitioners; 7. Who is responsible for performing each of the required tests and the required frequency for performing them; 8. An agreed method for timely communication of clinical findings and patient management between the two practitioners and the patient's nominated general practitioner.

Source: compiled during evaluation

3.8 The Minor Overview noted that tafluprost, which is on the Optometric Schedule of the PBS, is not included in the OBA approved list of Schedule 4 poisons that

optometrists are able to prescribe according to the Board's *Guidelines for Use of Scheduled Medicines*. (Appendix C of the Board Guidelines).

4 Consumer comments

- 4.1 The PBAC noted the input from the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) via the Consumer Comments facility on the PBS website. RANZCO's response stated that removal of the shared care arrangements would "result in; unnecessary diagnostic tests, misdiagnosis, inappropriate treatment management, risks to patient safety and increased health care costs." RANZCO estimated that the removal of shared care arrangements would result in a net increase in Commonwealth expenditure of \$58.7 million by 2020. This claim was based on "misdiagnosis of glaucoma by optometrists".
- 4.2 RANZCO requested that the following statement be added to the existing 'PBS Guidelines for Shared Care of Glaucoma Patients':
"The authorised optometrist must refer the patient to an ophthalmologist every 2 years as a minimum requirement for reassessment. Frequency of referrals might need to be higher and should be determined by collaborative arrangements with an ophthalmologist".

5 Estimated PBS usage & financial implications

- 5.1 The submission estimated minimal financial impact on the Commonwealth and claimed that the small increase in health expenditure may be balanced by savings resulting from improved health outcomes associated with earlier commencement of treatment.
- 5.2 The table below provides context regarding the extent of currently PBS subsidised usage of anti-glaucoma medicines prescribed by optometrists.

Medicines on the Optometric Schedule and the total PBS/RPBS services from June 2013 to July 2014 (prescribed by authorised optometrists)

Medicines	PBS/RPBS Usage
Betaxolol (0.25% and 0.5%)	311
Bimatoprost (bottle and unit doses)	2,727
Bimatoprost + Timolol (bottle and unit doses)	1,321
Brimonidine (0.15% and 0.2%)	1,942
Brimonidine + Timolol	1,096
Brinzolamide	2,232
Brinzolamide + Timolol	517
Dorzolamide	420
Dorzolamide + Timolol	1,001
Latanoprost	15,330
Latanoprost + Timolol	4,677
Pilocarpine 1%	55
Pilocarpine 2%	124
Pilocarpine 4%	19
Timolol (0.25%, 0.5%, 1%)	215
Travoprost	2,959
Timolol + Travoprost	1,748

Source: compiled during evaluation from PBS Item Reports: Date accessed 23.01.15
 URL: http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp

6 PBAC Outcome

6.1 The PBAC recommended that the NOTE for the following anti-glaucoma preparation when prescribed by an optometrist be amended to state 'For prescribing in accordance with Optometry Board of Australia guidelines':

- Betaxolol (0.25% and 0.5%)
- Bimatoprost (bottle and unit doses)
- Bimatoprost + Timolol (bottle and unit doses)
- Brimonidine (0.15% and 0.2%)
- Brimonidine + Timolol
- Brinzolamide
- Brinzolamide + Timolol
- Dorzolamide
- Dorzolamide + Timolol
- Latanoprost
- Latanoprost + Timolol
- Pilocarpine (1%, 2%, 4%)
- Timolol (0.25%, 0.5%, 1%)
- Travoprost
- Timolol + Travoprost

Further, the PBAC recommend removal of the 'PBS Guidelines for Shared Care of Glaucoma Patients' from the PBS Schedule, which is the document to which the NOTE referred.

6.2 The PBAC noted that, in December 2014, the Optometry Board of Australia (OBA) released revised Guidelines that allow optometrists to make an initial diagnosis and initiate treatment for chronic glaucoma with Schedule 4 anti-glaucoma medications,

on condition that a referral for ophthalmological assessment to confirm the diagnosis and advise on ongoing management is provided to the patient within four months. The PBAC noted that, under the Guidelines, there is no longer a requirement for an optometrist to work in shared care arrangement with an ophthalmologist to initiate treatment and prescribe anti-glaucoma medications.

- 6.3 The PBAC further noted that the submission stated, and documentary confirmation was provided, that the revised OBA Guidelines reflect the outcomes of an out-of-court settlement between the Optometry Board of Australia, RANZCO and the Australian Society of Ophthalmologists.
- 6.4 Although noting that there had been legal agreement between the relevant parties, the PBAC also noted RANZCO's consumer comment stated that removal of the shared care arrangements would "result in; unnecessary diagnostic tests, misdiagnosis, inappropriate treatment management, risks to patient safety and increased health care costs." Further, the PBAC noted RANZCO's request to add the statement requiring referral to an ophthalmologist every 2 years to the existing "PBS Guidelines for Shared Care of Glaucoma Patients".
- 6.5 The PBAC noted that the requested medicines can already be prescribed as private prescriptions by authorised optometrists in accordance with the revised OBA guidelines. Therefore the PBAC re-iterated its view from April 2011, that the issue for the Committee is PBS-subsidised access for patients by means of authorised health professionals approved to prescribe in the relevant state and territory jurisdictions, rather than work-force capability issues.
- 6.6 The PBAC further re-iterated its comments from April 2011 that the competency of optometrists to prescribe is the responsibility of the Optometry Board of Australia, and not the PBAC. The PBAC noted that the Optometry Board defines the educational requirements for designation as a prescriber, and also the professional standards to which optometrist prescribers must adhere, including through its revised 'Guidelines for use of scheduled medicines'.
- 6.7 The PBAC considered that allowing the requested items to be prescribed in accordance with the revised OBA guidelines would not change the appropriateness of its original recommendations to list the anti-glaucoma medicines on the PBS, including that it would not change the comparative effectiveness and cost-effectiveness of the relevant items.
- 6.8 As such, the PBAC recommended amendment of the current administrative advice 'NOTE' for optometrist prescribers to state "For prescribing in accordance with Optometry Board of Australia guidelines".
- 6.9 The PBAC noted that tafluprost, which is on the Optometric Schedule of the PBS, is not included in the OBA approved list of Schedule 4 poisons that optometrists are able to prescribe according to the Board's *Guidelines for Use of Scheduled Medicines*. The PBAC requested that the Department consult with OBA and Optometry Australia on this matter.

Outcome:

Recommended

7 Recommended listing

7.1 Amend NOTE as follows:

Brimonidine, brinzolamide, dorzolamide, betaxolol, timolol, bimatoprost, latanoprost, tafluprost and travoprost. (Item codes 5563T, 5534G, 5540N, 5543R, 5544T, 5551E, 10053D, 5541P, 5552F, 5549C, 5550D, 5548B, 2748P, 5546X)

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Optometrists
Note	Shared Care Model: <i>For prescribing in accordance with Optometry Board of Australia guidelines. by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.</i>

Bimatoprost + timololol, latanoprost + timolol, brimoidine + timolol, brinzolamide + timolol, dorzolamide + timolol, timolol + travoprost, and pilocarpine. (Item codes 5558M, 10108B, 5535H, 5562R, 5542Q, 5553G, 5555J, 5536J, 5537K, 5538L)

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Optometrists
Condition:	Elevated intra-ocular pressure
PBS Indication:	Elevated intra-ocular pressure
Clinical Criteria:	The condition must have been inadequately controlled with monotherapy, AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.
Note	Shared Care Model: <i>For prescribing in accordance with Optometry Board of Australia guidelines. by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.</i>

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The sponsor had no comment.