

# Medicines for the treatment of Glaucoma

## Drug utilisation sub-committee (DUSC)

*June 2016*

### **Abstract**

#### ***Purpose***

To review the utilisation of medicines used to treat glaucoma and elevated intraocular pressure. The DUSC requested a utilisation analysis of this group of medicines at its February 2016 meeting. The DUSC noted it had not reviewed the utilisation of these medicines for many years.

#### ***Date of listing on the Pharmaceutical Benefits Scheme (PBS)***

Most single-ingredient glaucoma medicines were listed on the PBS before 2004. A number of fixed dose combination products (FDCs) have been listed on the PBS between 2004 and 2015.

#### ***Data Source / methodology***

Data for glaucoma medicines were extracted from the DUSC and Department of Human Services (DHS) prescription databases from 2004 to 2015 (inclusive).

#### ***Key Findings***

- The number of PBS and Repatriation Schedule of Pharmaceutical Benefits (RPBS) prescriptions for glaucoma medicines has increased steadily between 2004 and 2015. Over 4.3 million prescriptions were supplied in 2015.
- FDCs, as a proportion of total glaucoma prescriptions, have increased from 9% to 30% of prescriptions between 2004 and 2015.
- Of glaucoma medicines supplied on the PBS between 2010 and 2015, ophthalmologists prescribed more than half; general practitioners prescribed 38%, and optometrists prescribed approximately 1% of prescriptions. The number of prescriptions supplied by optometrists increased between 2010 and 2015.
- 33% of patients who started a FDC between July 2014 and December 2015 had not received a single ingredient glaucoma medicine in the two years prior to starting a FDC.
- R/PBS expenditure for glaucoma medicines increased from \$76.95 million in 2004 to a peak of \$112.77 million in 2011. Expenditure decreased thereafter to \$99.27 million in 2015.

## **Purpose of analysis**

To review the utilisation of medicines used to treat glaucoma and elevated intraocular pressure. The DUSC requested an utilisation analysis of this group of medicines at its February 2016 meeting. The DUSC noted it had not reviewed the utilisation of these medicines for many years.

Acetazolamide was not included in this analysis because it can be used for a variety of other conditions.<sup>1</sup>

## **Background**

### **Pharmacology**

Medicines used to treat glaucoma aim to reduce intraocular pressure (IOP), the pressure inside the eye. Glaucoma medicines reduce IOP by increasing aqueous humour outflow or decreasing aqueous humour production. There are five classes of glaucoma medicines. Prostaglandin analogues and cholinergic medicines increase the outflow of aqueous humour. Beta-blockers and carbonic anhydrase inhibitors decrease the production of aqueous humour. Alpha2-agonists increase aqueous humour outflow and decrease its production.<sup>2</sup>

### **Therapeutic Goods Administration (TGA) approved indications**

The majority of single-ingredient glaucoma medicines are indicated for the treatment of high intraocular pressure and open angle glaucoma.<sup>3-11</sup>

Apraclonidine, an alpha2-agonist is indicated to control intraocular pressure in glaucoma patients on maximally tolerated glaucoma therapy for a period of 3 months.<sup>12</sup>

Timolol is also indicated for use by aphakic patients (patients without lenses) with glaucoma.<sup>10</sup>

Fixed-dose combination (FDC) glaucoma medicines are indicated for the reduction of high IOP in patients with ocular hypertension or open-angle glaucoma where monotherapy provides insufficient reduction of IOP.<sup>13-18</sup>

### **Dosage and administration**

Table 1 presents the frequency of dosing of glaucoma medicines.

**Table 1: Dosage and administration of glaucoma medicines**

| Once daily  | Twice daily   | Three times daily  |
|---|---|--|
| <b>Prostaglandin analogues</b><br>Bimatoprost<br>Latanoprost<br>Tafluprost<br>Travoprost<br><b>Beta blockers</b><br>Timolol gel ( <i>Nyogel</i> <sup>®</sup> )<br>Timolol extended release formulation ( <i>Timoptol-XE</i> <sup>®</sup> )<br><b>Combination products</b><br>Bimatoprost and timolol<br>Latanoprost and timolol<br>Travoprost and timolol | <b>Beta blockers</b><br>Betaxolol<br>Timolol<br><b>Alpha2-agonists</b><br>Brimonidine<br><b>Carbonic anhydrase inhibitors</b><br>Brinzolamide<br><b>Combination products</b><br>Bimatoprost and timolol<br>Brimonidine and timolol<br>Brinzolamide and timolol<br>Dorzolamide and timolol | <b>Alpha2-agonists</b><br>Apraclonidine<br><b>Carbonic anhydrase inhibitors</b><br>Dorzolamide<br><b>Anticholinergics</b><br>Pilocarpine |

Source: Product Information for Iopidine (apraclonidine), Betoptic (betaxolol), Lumigan (bimatoprost), Ganfort (bimatoprost with timolol), Alphagan (brimonidine), Simbrinza (brimonidine with brinzolamide), Combigan (brimonidine with timolol), Azopt (brinzolamide), Azarga (brinzolamide with timolol), Trusopt (dorzolamide), Cosopt (dorzolamide with timolol), Xalatan (latanoprost), Xalacom (latanoprost with timolol), Isopto Carpine (pilocarpine), Saflutan (tafluprost), Timoptol (timolol), Nyogel (timolol gel), Timoptol XE (timolol), Travatan (Travoprost) and Duotrav (travoprost with timolol)

The current Product Information (PI) and Consumer Medicine Information (CMI) are available from the [TGA](#).

## Clinical situation

The glaucomas are a group of diseases where the optic nerve is progressively damaged, causing vision loss. Chronic open angle glaucoma is the most common type of glaucoma in the western countries. Glaucoma is typically asymptomatic until there is a substantial amount of damage to the nerves.<sup>19</sup> Up to 37% of optic nerve fibres need to be lost before visual field defects can be detected.<sup>2</sup> Glaucoma initially damages side vision. The undamaged or less affected eye may compensate and mask the extent of vision loss.<sup>20</sup>

Reduction of intraocular pressure reduces visual field loss. This is true of glaucoma patients who have ocular hypertension as well as patients who have normal tension glaucoma.<sup>2</sup> Intraocular hypertension is generally defined as pressure greater than 21 mm Hg.<sup>21</sup> It has been estimated that untreated patients with mild glaucoma will be blind in at least one eye at 23 years, compared to 35 years for treated patients.<sup>22</sup> Treating patients who have elevated intraocular pressure but no damage to the optic nerve or visual field has shown to reduce the development of primary open angle glaucoma at five years from 9.5% to 4.4%.<sup>23</sup>

The Blue Mountains Eye Study<sup>24</sup> identified definite or probable glaucoma in 3.0% (95% CI: 2.5 – 3.6) of patients aged 50 years and older. Prevalence was 0.4% for people younger than 60 years, increasing exponentially to 11.5% for patients aged 80 years and older. The study also identified that 51% of patients were undiagnosed. The prevalence of ocular hypertension was 3.7% (95% CI: 1.7 – 2.7). The prevalence of ocular hypertension did not increase significantly with age. The Melbourne Visual Impairment Project<sup>25</sup> assessed a random sample of Melbourne residents aged 40 years and older. The prevalence of definite glaucoma was 1.7% (95% CI: 1.21 – 2.21). Intraocular hypertension was found in 0.9% of the group, one-third of whom did not have clinical signs of glaucoma.

The National Health and Medical Research Council Guidelines for the Screening, Prognosis, Diagnosis, Management and Prevention of Glaucoma were published in 2010. The guidelines recommend the use of a once-daily topical prostaglandin analogue for first line treatment. Treatment should commence in one eye only to allow the other eye to be used as a control. The eye with higher pressure should be selected for initial treatment. Response should be checked within two to six weeks.

FDC products should be considered when more than one drug is required. This may improve compliance with the treatment regimen. Oral acetazolamide may be used where patients are unable to administer eye drops or further reductions in intraocular pressure are required. Systemic beta-blockers are not as effective as topical medications.

### **PBS listing details (as at 1 May 2016)**

There were 92 items for glaucoma listed in the May 2016 PBS Schedule. The majority of products have two item codes: one for medical practitioners and one for optometrists.

**Table 2: PBS listing of glaucoma medicines (as of 1 May 2016)**

| Item                     | Name, form & strength, pack size                            | Max. quant. | Rpts | DPMQ                 | Brand name and manufacturer   |
|--------------------------|---|-------------|------|----------------------|---|
| 8083K                    | apraclonidine 0.5% eye drops, 10 mL                         | 1           | 2    | \$39.73              | Iopidine 0.5%<br>Alcon Laboratories (Australia) Pty Ltd   |
| 5298W<br>5563T<br>(OP)   | brimonidine tartrate 0.15% eye drops, 5 mL                  | 1           | 5    | \$22.35              | Alphagan P 1.5<br>Allergan Australia Pty Limited  |
| 8351M<br>5534G<br>(OP)   | brimonidine tartrate 0.2% eye drops, 5 mL                   | 1           | 5    | \$22.35/<br>\$23.77  | Enidin<br>Allergan Australia Pty Limited<br>Alphagan<br>Allergan Australia Pty Limited                  |
| 8826M<br>5535H<br>(OP)   | brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL    | 1           | 5    | \$27.47              | Combigan<br>Allergan Australia Pty Limited  |
| 2595N<br>5536J<br>(OP)   | pilocarpine hydrochloride 1% eye drops, 15 mL               | 1           | 5    | \$15.73              | Isopto Carpine<br>Alcon Laboratories (Australia) Pty Ltd  |
| 2596P<br>5537K<br>(OP)   | pilocarpine hydrochloride 2% eye drops, 15 mL               | 1           | 5    | \$16.82              | Isopto Carpine<br>Alcon Laboratories (Australia) Pty Ltd  |
| 2598R<br>5538L           | pilocarpine hydrochloride 4% eye drops, 15 mL               | 1           | 5    | \$19.30              | Isopto Carpine<br>Alcon Laboratories (Australia) Pty Ltd  |
| 8483L<br>5540N<br>(OP)   | brinzolamide 1% eye drops, 5 mL                             | 1           | 5    | \$24.64 /<br>\$26.92 | BrinzoQuin<br>Alcon Laboratories (Australia) Pty Ltd<br>Azopt<br>Alcon Laboratories (Australia) Pty Ltd |
| 10536M<br>10547D<br>(OP) | brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL | 1           | 5    | \$26.98              | Simbrinza 1%/0.2%<br>Alcon Laboratories (Australia) Pty Ltd   |
| 3438Y<br>5562R<br>(OP)   | brinzolamide 1% + timolol 0.5% eye drops, 5 mL              | 1           | 5    | \$28.21              | Azarga<br>Alcon Laboratories (Australia) Pty Ltd  |
| 8488R<br>5541P<br>(OP)   | dorzolamide 2% (20 mg/mL) eye drops, 5 mL                   | 1           | 5    | \$21.29              | Trusamide<br>Aspen Pharma Pty Ltd<br>Trusopt Merck Sharp & Dohme (Australia) Pty Ltd                    |

| Item                     | Name, form & strength, pack size                                   | Max. quant. | Rpts | DPMQ                | Brand name and manufacturer  |
|--------------------------|--|-------------|------|---------------------|--|
| 8567X<br>5542Q<br>(OP)   | dorzolamide 2% + timolol 0.5% eye drops, 5 mL                      | 1           | 5    | \$25.58             | Cosdor<br>Aspen Pharma Pty Ltd<br>Dorzolamide/Timolol Sandoz 20/5<br>Sandoz Pty Ltd<br>Cosopt<br>Merck Sharp & Dohme (Australia) Pty Ltd |
| 2811Y<br>5543R<br>(OP)   | betaxolol 0.25% eye drops, 5 mL                                    | 1           | 5    | \$17.68/<br>\$20.76 | Betoptic S<br>Alcon Laboratories (Australia) Pty Ltd   |
| 2825Q<br>5544T<br>(OP)   | betaxolol 0.5% eye drops, 5 mL                                     | 1           | 5    | \$17.68             | BetoQuin<br>Alcon Laboratories (Australia) Pty Ltd<br>Betoptic<br>Alcon Laboratories (Australia) Pty Ltd                                 |
| 8803H<br>5546X<br>(OP)   | timolol 0.1% eye gel, 5 g  | 1           | 5    | \$16.03             | Nyogel<br>Aspen Pharmacare Australia Pty Limited   |
| 1925H<br>5549C<br>(OP)   | timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL                        | 1           | 5    | \$14.87             | Timoptol XE<br>Merck Sharp & Dohme (Australia) Pty Ltd   |
| 1926J<br>5550D<br>(OP)   | timolol 0.5% (5 mg/mL) eye drops, 2.5 mL                           | 1           | 5    | \$15.54             | Timoptol XE<br>Merck Sharp & Dohme (Australia) Pty Ltd   |
| 1279H<br>5548B<br>(OP)   | timolol 0.5% (5 mg/mL) eye drops, 5 mL                             | 1           | 5    | \$15.54/<br>\$18.18 | Tenopt<br>Aspen Pharma Pty Ltd<br>Timoptol<br>Merck Sharp & Dohme (Australia) Pty Ltd  |
| 8620Q<br>5551E<br>(OP)   | bimatoprost 0.03% eye drops, 3 mL                                  | 1           | 5    | \$40.08             | Lumigan<br>Allergan Australia Pty Limited  |
| 10046R<br>10053D<br>(OP) | bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses                | 1           | 5    | \$35.33             | Lumigan PF<br>Allergan Australia Pty Limited   |
| 10107Y<br>10108B<br>(OP) | bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses | 1           | 5    | \$39.06             | GANfort PF 0.3/5<br>Allergan Australia Pty Limited   |

| Item                   | Name, form & strength, pack size                      | Max. quant. | Rpts | DPMQ    | Brand name and manufacturer                         |
|------------------------|---|-------------|------|---------|---|
| 9464D<br>5558M<br>(OP) | bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL      | 1           | 5    | \$44.54 | Ganfort 0.3/5<br>Allergan Australia Pty Limited     |
| 8243W<br>5552F<br>(OP) | latanoprost 0.005% eye drops, 2.5 mL                  | 1           | 5    | \$22.86 | Numerous brands                                     |
| 8895E<br>5553G<br>(OP) | latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL   | 1           | 5    | \$27.31 | Numerous brands                                     |
| 2755B<br>2748P<br>(OP) | tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses  | 1           | 5    | \$34.25 | Saflutan<br>Merck Sharp & Dohme (Australia) Pty Ltd |
| 9057Q<br>5555J<br>(OP) | timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL    | 1           | 5    | \$44.54 | Duotrav<br>Alcon Laboratories (Australia) Pty Ltd   |
| 8597L<br>5554H<br>(OP) | travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL | 1           | 5    | \$40.08 | Travatan<br>Alcon Laboratories (Australia) Pty Ltd  |

Source: May 2016 Schedule of Pharmaceutical Benefits. Available from the [PBS website](#).

OP = Optometrist listing for prescribing in accordance with Optometry Board of Australia guidelines

### **Restrictions**

All single-ingredient glaucoma medicines, excluding apraclonidine, have unrestricted listings for both medical practitioners and optometrists. Apraclonidine has a restricted benefit listing for the short-term reduction of intra-ocular pressure for patients on maximally tolerated anti-glaucoma therapy. Combination products are listed for open-angle glaucoma or ocular hypertension that is not adequately controlled by monotherapy. Optometrists are required to prescribe in accordance with Optometry Board of Australia guidelines.

For details of the current PBS listings refer to the [PBS website](#).

### **Date of listing on PBS**

Most single-ingredient glaucoma medicines were listed on the PBS before 2004.

New listings from 1 January 2004 are listed in Table 3.

**Table 3: New glaucoma medicines listed on the PBS**

| Date           | Drug (brand)   |
|----------------|--|
| April 2005     | Timolol eye gel (Nyogel®)  |
| April 2006     | Latanoprost with timolol (Xalacom®) <sup>a</sup>                   |
| December 2006  | Travoprost with timolol (Duotrav®)                                 |
| March 2009     | Brimonidine with timolol (Combigan®)                               |
| March 2009     | Dorzolamide with timolol (Cosopt®)                                 |
| August 2009    | Bimatoprost with timolol (Ganfort®)                                |
| August 2010    | Brinzolamide with timolol (Azarga®)                                |
| November 2010  | Brimonidine (Alphagan P®)  |
| September 2013 | Tafluprost (Saflutan®)   |
| March 2014     | Bimatoprost individual dose packs (Lumigan PF®)                    |
| July 2014      | Bimatoprost with timolol individual dose packs (GANfort PF 0.3/5®) |
| December 2015  | Brinzolamide with brimonidine (Simbrinza 1%/0.2%®)                 |

Source: Department of Health PBS Schedule Summary database, extracted March 2016

<sup>a</sup> Previously listed on RPBS.

### ***Changes to listing***

Table 4 lists the products that were removed from the PBS between January 2004 and December 2015.

**Table 4: Glaucoma medicines removed from the PBS**

| Date           | Drug (brand)                        |
|----------------|-------------------------------------|
| December 2004  | Timolol with pilocarpine (Timpilo®) |
| December 2004  | Acetazolamide injection (Diamox®)   |
| April 2006     | Carbachol (Isopto Carbachol®)       |
| December 2006  | Pilocarpine (Pilopt®)               |
| January 2008   | Pilocarpine (P.V. Carpine®)         |
| September 2008 | Dipivefrine (Propine®)              |
| December 2008  | Levobunolol (Betagan®)              |
| May 2014       | Timolol (Tenopt®)                   |

Source: Department of Health PBS Schedule Summary database, extracted March 2016

There have been a number of changes to the PBS restrictions. In **July 2009**, the restrictions for prostaglandin analogue with timolol FDCs were changed to also allow patients whose condition was not sufficiently controlled with prostaglandin analogues to start an FDC. The restrictions previously required the condition to be not adequately controlled with timolol.

In **July 2010**, the restrictions of timolol-containing glaucoma medicines were changed to remove the requirement that intra-ocular pressure is not adequately controlled with

timolol. The restrictions were changed to include all patients whose condition was not adequately controlled with monotherapy.

### **Optometrist prescribing**

In **January 2008**, optometrists were permitted to prescribe some items on the PBS. At the time this did not include medicines for glaucoma. Optometrists were required to be accredited to prescribe under relevant State or Territory legislation and approved as PBS prescribers. Refer to the January 2008 PBS Schedule Summary of Changes for full details of the listings.

In **March 2009**, topical anti-glaucoma medicines were added to the PBS medicines for authorised optometrists under shared care arrangements with an ophthalmologist. Patients who had a provisional diagnosis of glaucoma from their optometrist were required to be referred to an ophthalmologist for confirmation of diagnosis and development of a written management plan. Following confirmation of diagnosis and development of a treatment plan, authorised optometrists could monitor patients and prescribe topical medication under the PBS. Periodic review was required to show the treatment was effective. Changes to management were to be initiated following consultation between practitioners. Further information on these arrangements is available in the General Statement for Topical Anti-Glaucoma Drugs Prescribed by Authorised Optometrists as Pharmaceutical Benefits in the March 2009 PBS Schedule.

In **March 2015**, the PBAC considered a submission by Optometry Australia to remove the requirement for optometrists to have a formalised shared care arrangement with an ophthalmologist to prescribe glaucoma medicines on the PBS; to reflect the Optometry Board of Australia's revised guidelines that were released in December 2014. The revised guidelines enabled endorsed optometrists to diagnose and initiate treatment for chronic glaucoma. A referral for ophthalmological assessment for confirmation of diagnosis and advice on management is to be provided to the patient within four months. The PBAC noted that optometrists are able to prescribe glaucoma medicines as private prescriptions. The PBAC recommended the change and 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. For further details refer to the Anti-glaucoma medicines Public Summary Document from the March 2015 PBAC meeting. This change was implemented in **July 2015**. The notes to the restrictions of optometrist listings state "For prescribing in accordance with Optometry Board of Australia guidelines".

Current PBS listing details are available from the [PBS website](#).

## **Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)**

### **Latanoprost with timolol (2005)**

A submission to list latanoprost with timolol was rejected by the PBAC in July 2001 due to insufficient evidence of additional benefit over latanoprost monotherapy. A July 2005 resubmission was deferred.

For further details refer to the [Public Summary Document](#) from the July 2005 PBAC meeting.

In November 2005, the PBAC recommended the listing of latanoprost with timolol. The submission was able to show the FDC reduced intraocular pressure by at least 1.5 mm Hg compared to latanoprost monotherapy. This was the magnitude of reduction that was considered clinically relevant by the PBAC.

For further details refer to the [Public Summary Document](#) from the November 2005 PBAC meeting.

### **Travoprost with timolol (July 2006 and March 2007)**

The PBAC recommended the listing of travoprost with timolol for the reduction of intraocular pressure in patients with open angle glaucoma or ocular hypertension not adequately controlled with timolol or travoprost. The listing was recommended on a cost-minimisation basis with latanoprost with timolol.

For further details refer to the Public Summary Document from the July 2006 PBAC meeting.

In March 2007, the PBAC recommended a change to the restriction to allow patients not achieving an adequate response to latanoprost to use travoprost with timolol.

For further details refer to the [Public Summary Document](#) from the March 2007 PBAC meeting.

### **Bimatoprost with timolol (March 2009)**

The PBAC recommended the listing of bimatoprost with timolol maleate on the PBS on a cost-minimisation basis compared with its constituent components given concomitantly. As requested by the sponsor, the PBAC recommended changing the wording of the restrictions for all PBS-listed timolol with prostaglandin analogue combinations so that patients who are on a timolol/prostaglandin analogue combination do not have to return to monotherapy with timolol prior to a change in the combination eye drop.

For further details refer to the [Public Summary Document](#) from the March 2009 PBAC meeting.

### **Brinzolamide with timolol (March 2010)**

The PBAC recommended the listing of brinzolamide with timolol eye drops for elevated intraocular pressure due to open angle glaucoma/ocular hypertension in a patient in whom this condition is not adequately controlled with monotherapy. The listing was recommended on a cost-minimisation basis against the individual components and against the combination product dorzolamide with timolol.

The PBAC also recommended a restriction wording of “elevated intra-ocular pressure in a patient with open angle glaucoma/ocular hypertension not adequately controlled with monotherapy” be applied to all restricted benefit listings of all combination eye drops containing an alpha-agonist with timolol, a carbonic anhydrase inhibitor with timolol or a prostaglandin/prostamide analogue with timolol. The PBAC considered that the use of a combination product in a patient whose elevated intra-ocular pressure due to open angle glaucoma or ocular hypertension is not adequately controlled on monotherapy is consistent with current guidelines which no longer recommend timolol as the first line therapy for all patients.

For further details refer to the [Public Summary Document](#) from the March 2010 PBAC meeting.

### **Tafluprost (March 2012)**

The PBAC recommended the listing of tafluprost, in a preservative-free (PF) formulation, as an unrestricted benefit in the general and optometrical schedules. The submission claimed the product had superior tolerability compared to latanoprost. The PBAC did not accept this claim. The incidence of adverse events was higher in the tafluprost PF formulation compared to latanoprost PF and the tafluprost formulation containing a preservative. The listing was recommended at a lower price than latanoprost due to the trials not demonstrating non-inferiority.

For further details refer to the [Public Summary Document](#) from the March 2012 PBAC meeting.

### **Dorzolamide with timolol (July 2012)**

The PBAC recommended the listing of dorzolamide with timolol PF eye drops for the reduction of elevated intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension that is not adequately controlled with monotherapy. The listing was recommended on a cost-minimisation basis with the standard formulation which contains preservatives. The PF product was not listed on the PBS.

For further details refer to the [Public Summary Document](#) from the July 2012 PBAC meeting.

### **Bimatoprost and timolol PF (March 2014)**

The PBAC recommended the listing of bimatoprost 0.03% + timolol 0.5% PF eye drops on the PBS as a Restricted Benefit for elevated intraocular pressure that is inadequately

controlled by monotherapy. [REDACTED]

[REDACTED] There is no Public Summary Document for this consideration.

### **Brinzolamide and brimonidine (July 2015)**

The PBAC recommended the Restricted Benefit listing of brinzolamide with brimonidine FDC on a cost-minimisation basis against the mixed comparator of dorzolamide with timolol FDC and the individual components of brinzolamide and brimonidine. Dorzolamide with timolol was the least expensive of FDCs containing either a carbonic anhydrase inhibitor or alpha agonist with timolol. The PBAC considered patients using the individual components of brinzolamide and brimonidine would contribute to 12.7% of the patient population. The PBAC noted it could not recommend the brinzolamide + brimonidine FDC for listing on the PBS at a higher price than alternative therapies, unless it was satisfied that it provides a significant improvement in efficacy or reduction of toxicity over the alternative therapies for some patients. The PBAC noted that brinzolamide and brimonidine used concomitantly was the comparator for patients who could not tolerate timolol. This was estimated to be 12.7% of the population based on an abstract by Spooner et al (2002).

For further details refer to the [Public Summary Document](#) from the July 2015 PBAC meeting.

### **Previous reviews by the DUSC**

DUSC has not assessed the utilisation of glaucoma medicines for many years.

In September 2006, DUSC undertook a predicted versus actual analysis of timolol gel (Nyogel®) utilisation one year after its listing. Utilisation was higher than predicted by the sponsor.

In August 2003, DUSC assessed the utilisation of dorzolamide, brinzolamide and latanoprost. Prescriptions for glaucoma medicines increased from 2.7 million in the year February 2000 to January 2001 to 3.2 million in the year February 2002 to January 2003. Latanoprost accounted for 43% of PBS subsidised and under co-payment prescriptions and 63% of PBS benefits paid for glaucoma medicines. The market share of beta-blocker prescriptions decreased from 44% to 34% during the same two year period.

### **Methods**

The analyses used data from the DUSC database and the Department of Human Services (DHS) Supplied Prescriptions database. The DHS Supplied prescriptions database includes data submitted to DHS for payment of a PBS/RPBS subsidy by the Government. This database includes actual under co-payment prescription data from 1 April 2012. This database includes a de-identified patient identifier number that identifies prescriptions supplied to a single patient. This allows for patients to be classified as new patients and to identify prior treatments. The DHS Supplied prescriptions database is used for patient level

analyses and prescriber data. The DUSC database combines data on PBS prescriptions submitted to the DHS with an estimate of under patient co-payment prescriptions based on dispensing data from a sample of pharmacies to the end of August 2012. This was replaced by actual under patient co-payment prescription data from 1 April 2012. The DUSC database is used for analyses of prescriptions and R/PBS expenditure.

The analysis of first glaucoma medicine was performed for concession patients only. Patients were considered concession patients if they had not received a general prescription in the two years before starting their first glaucoma medicine. General prescriptions included prescriptions subsidised to the general patient co-payment and, after April 2012, under co-payment prescriptions. A limitation of the method is that it may mistime when patients started a medicine. For example, a general patient who started a glaucoma medicine priced below the general co-payment in the two years before attaining concession status will be counted as a new patient when they receive their first concession prescription. This delay may also misclassify the medicine with which they started treatment if they changed medicine during this time. This error is reduced for patients who start after April 2012 when DHS started collecting under co-payment data. After April 2012, this error will be minimal except in cases where patients may have received private prescriptions before starting PBS supply. The definition of concession patients used for the analysis may exclude some RPBS beneficiaries who receive their glaucoma medicines as an RPBS benefit but receive other medicines as a general beneficiary.

The analysis of prior treatment was undertaken for patients who started an FDC between July 2014 and December 2015. The purpose of this analysis was to understand patterns of switching to FDCs in general and concession patients. Patients were considered to be newly starting an FDC if they were not supplied an FDC in the previous two years. This time period was chosen because two full years of under co-payment data are available for the lookback at prior treatments.

Published defined daily doses (DDDs) are available for glaucoma medicines. The World Health Organisation (WHO) DDDs for glaucoma medicines are the number of drops required to treat two eyes each day converted to millilitres. It is assumed one drop is 0.05 mL.<sup>26</sup> This method was not used because the duration of multi-dose eye drops use is typically limited to 28 days' use to prevent antimicrobial contamination. Some products listed on the PBS provide more volume than can be used during a 28 day period.

Some analyses result in small values relating to five or fewer patients or prescriptions over a time period. These results are suppressed or presented as an aggregate over a longer period to protect privacy.

As this analysis uses date of supply prescription data, there may be small differences compared with publicly available Department of Human Services (DHS) Medicare date of

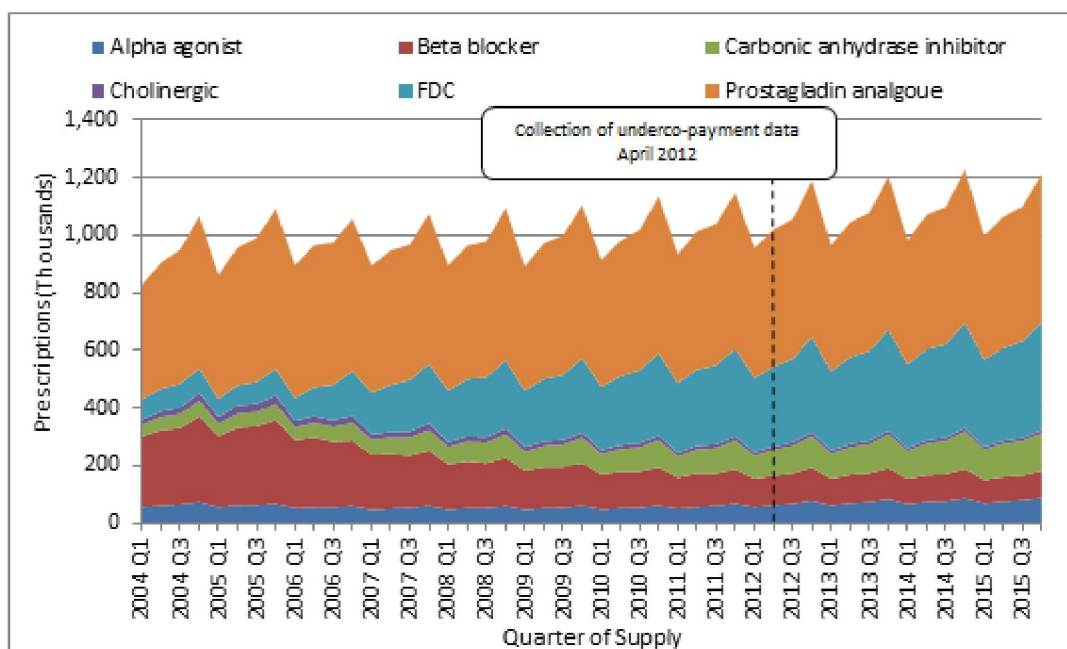
processing data.<sup>1</sup> The publicly available DHS Medicare data only includes subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included.

## Results

### Analysis of drug utilisation

#### Overall utilisation

Figure 1 presents the number of prescriptions for glaucoma medicines by drug class for single ingredient medicines. FDCs are presented as a single category.



**Figure 1: Glaucoma prescriptions by drug type**

Source: DUSC Database, extracted March 2016.

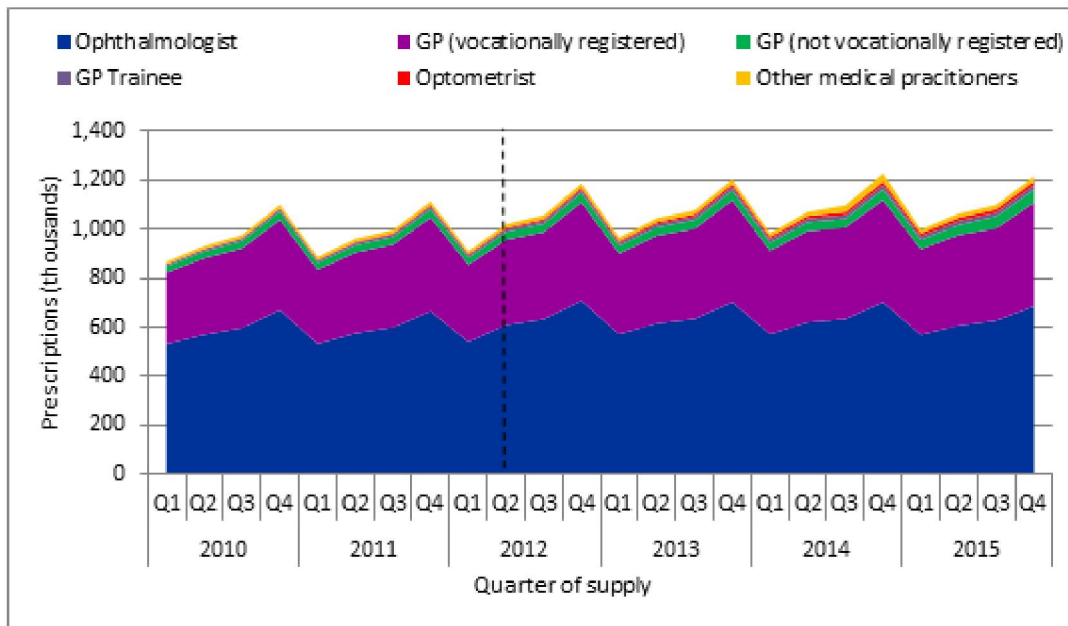
Note: Data presented excludes private prescriptions.

The number of glaucoma medicine prescriptions supplied on the R/PBS has increased steadily between 2004 and 2015. Over 4.3 million prescriptions were supplied in 2015. Prostaglandin analogues have the largest number of prescriptions throughout the period. The number of single ingredient beta-blockers and cholinergic product prescriptions has decreased. Over one million more FDC prescriptions were supplied in 2015 compared to 2004. As a proportion of total glaucoma prescriptions, FDCs have increased from 9% to 30% of prescriptions between 2004 and 2015. The data presented does not include private prescriptions. The estimate of private prescriptions accounted for 0.4% of glaucoma prescriptions supplied between 2004 and the third quarter of 2012, the last quarter for which these data are available.

<sup>1</sup> PBS statistics. Australian Government Department of Human Services Medicare. Canberra. Available from <<http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp>>.

### Utilisation by prescriber type

Figure 2 presents the distribution of R/PBS prescriptions by prescribing practitioner type.



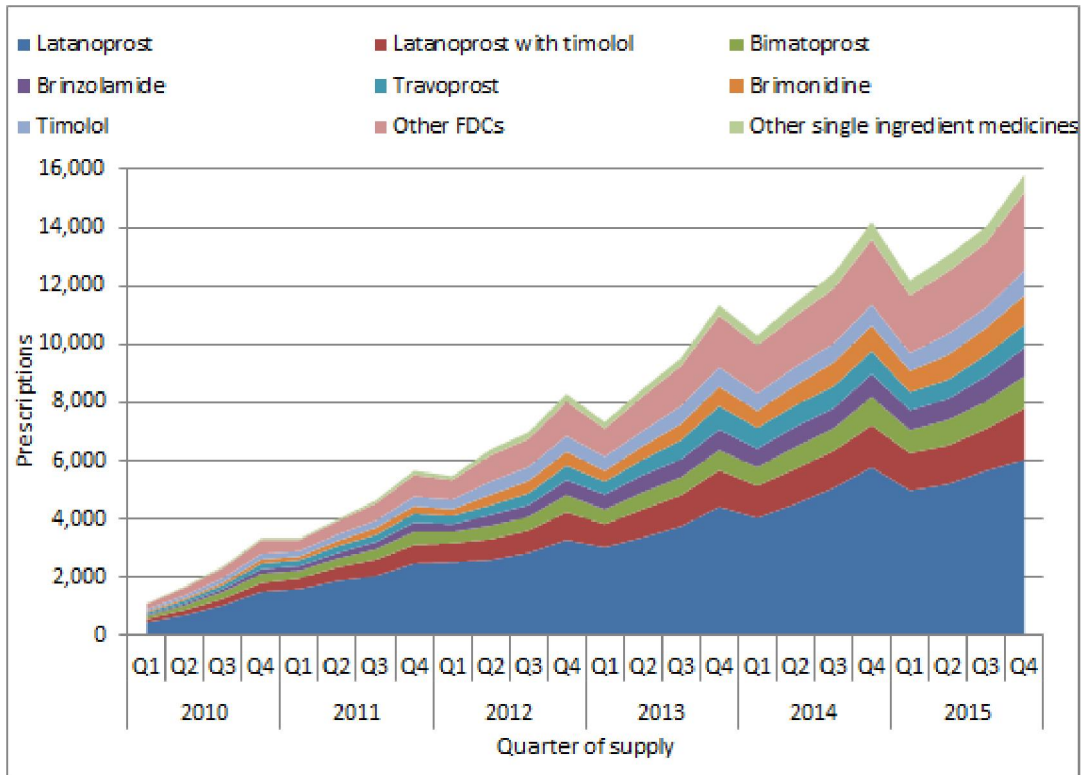
**Figure 2: Prescriptions by prescriber type**

Source: Department of Human Services Supplied Prescriptions Database, extracted March 2016.

Note: This data does not include private prescriptions or under co-payment prescriptions before April 2012. GP Unclassified is included under other medical practitioners.

Ophthalmologists prescribe more than half of all R/PBS prescriptions for glaucoma medicines. GPs, excluding GP trainees, prescribed 38% of prescriptions that were supplied during the period. Optometrists provided approximately 1% of prescriptions during the period. All other medical practitioners, including GP trainees, prescribed 2.4% of prescriptions supplied during the period.

Figure 3 presents optometrist prescribing by medicine.



**Figure 3: Optometrist prescribing by drug**

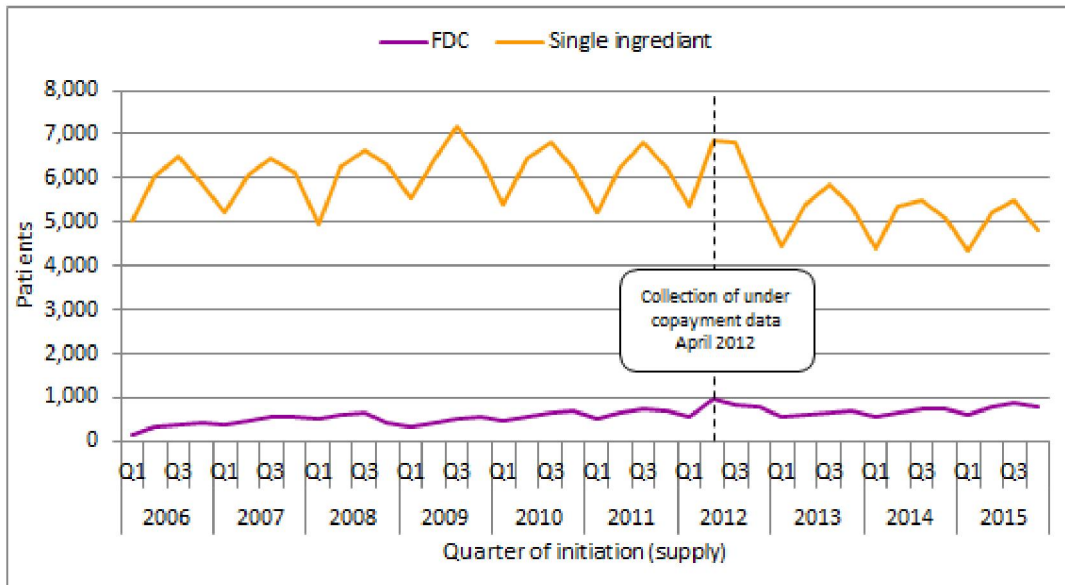
Source: Department of Human Services Supplied Prescriptions Database, extracted March 2016.

Latanoprost was the medicine most frequently prescribed by optometrists over the period. Approximately three quarters of optometrist prescriptions were for single ingredient medicines. The overall volume of optometrist prescriptions has grown over six-fold from 2010 to 2015. The removal of the requirement for shared care arrangement with ophthalmologists in 2015 does not appear to have an immediate impact in the first two quarters following the change.

***Utilisation by first glaucoma medicine***

The following analyses examine which glaucoma medicines are used when patients first start treatment. This analysis uses a concessional cohort of patients who were only supplied concession prescriptions in the two years before starting a glaucoma medicine (refer to the [Methods](#) section for further information). Patients were considered new to treatment if they had not received a glaucoma medicine in the previous two years.

Figure 4 presents the number of concessional patients starting treatment with glaucoma medicines by the type of medicine with which they started treatment: a single ingredient medicine or an FDC.

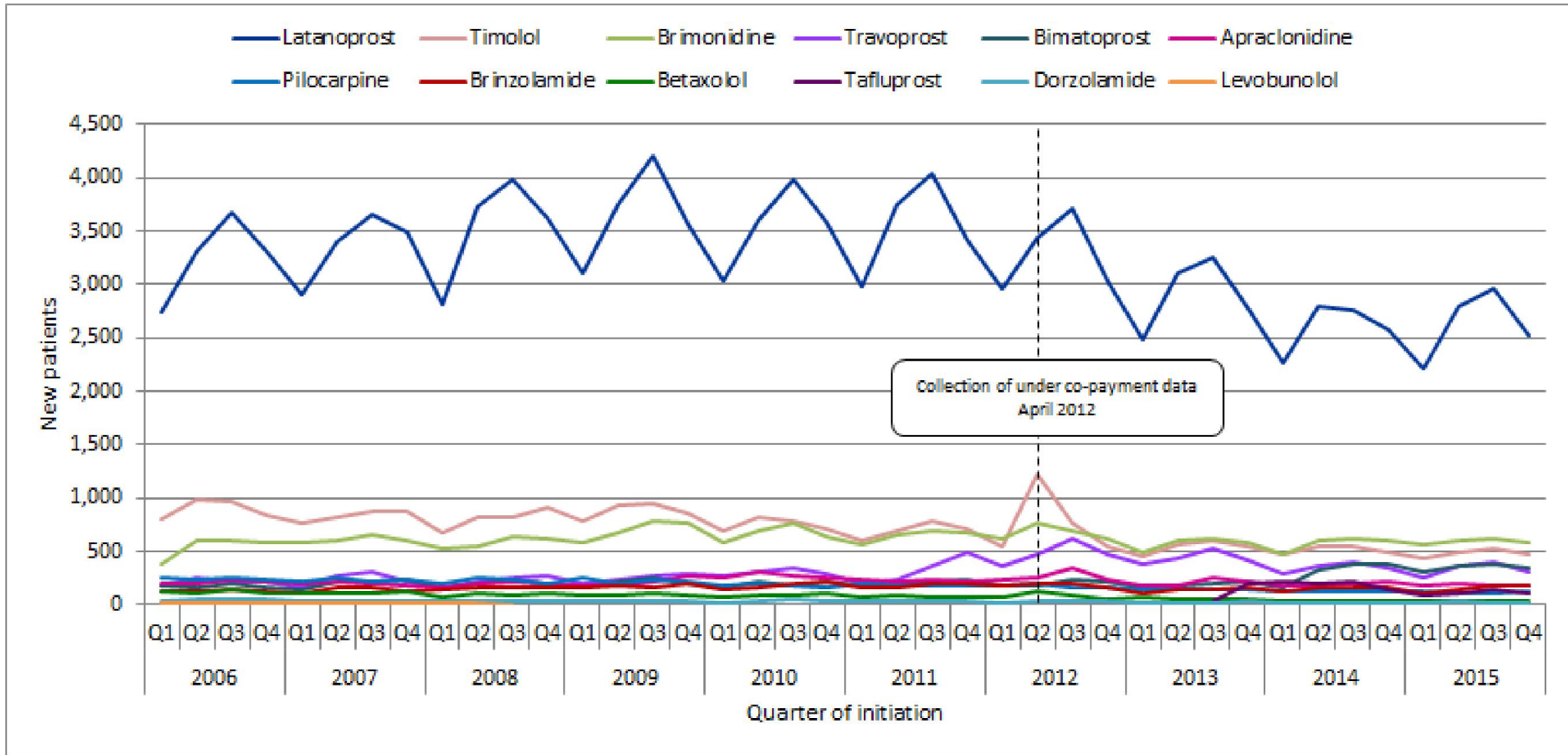


**Figure 4: Starting glaucoma medicine by drug type**

Source: Department of Human Services Supplied Prescriptions Database, extracted March 2016.

The majority of patients who start a glaucoma medicine do so with a single ingredient medicine. A small, but increasing, group of people appear to be starting treatment with a combination product. The number of patients starting treatment with a single ingredient product each quarter decreased after 2012.

Figure 5 presents the single ingredient medicines that were used as a first glaucoma treatment.



**Figure 5: Starting glaucoma medicine by drug type**

Source: Department of Human Services Supplied Prescriptions Database, extracted March 2016.

Note: Results for dipivefrine and carbachol are suppressed due to small patient numbers. A total of 23 patients started either dipivefrine or carbachol between January 2006 and June 2008. The number of patients starting levobunolol was rounded up to five due to small patient numbers.

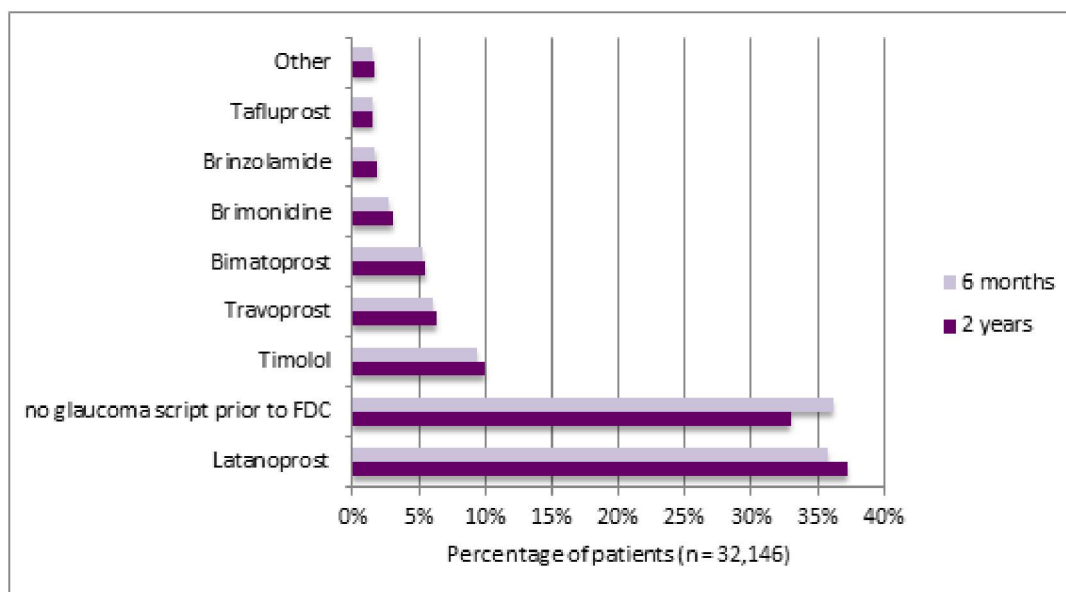
Latanoprost was the most frequently supplied first medicine. It accounted for over 50% of first prescriptions in the period from 2006 to 2015. Timolol was the second most frequently supplied medicine in the earlier years.

Brimonidine became the second most frequently supplied first medicine in 2013. Latanoprost, timolol, brimonidine, travoprost and bimatoprost accounted for 80% of first prescriptions during the period. There is an apparent increase in the number of patients starting timolol in the second quarter of 2012. *This may be due incomplete under co-payment data capture prior to April 2012.* Refer to the [Methods](#) section for further information.

The apparent number of patients starting latanoprost decreases after 2012. The reduced number of patients starting latanoprost is also reflected in Figure 4 with a reduced number of patients starting single ingredient medicines. *The cause of this decrease is unclear.*

**Prior treatment analysis: FDCs**

This analysis examined which glaucoma medicines patients used before starting their first FDC. Figure 6 presents the last medicine used within two years of starting an FDC and a sensitivity analysis of medicines used in the six months prior to starting an FDC.



**Figure 6: Prior treatment before FDC**

Source: Department of Human Services Supplied Prescriptions Database, extracted April 2016.

Note: Other includes apraclonidine, pilocarpine, betaxolol and dorzolamide.

There were 32,146 patients who started an FDC for glaucoma between July 2014 and December 2015. Latanoprost was the mostly frequently used prior treatment before starting an FDC when a two year lookback period. No previous medicine was the second most frequent category. Timolol was the third most frequent prior treatment. Prostaglandin analogues accounted for approximately 50% of prior treatment for both lookback periods.

No glaucoma medicine was the mostly frequently used prior treatment when a six month lookback period was used, followed by latanoprost, and timolol. There is only small variation in numbers between medicines used in the previous two years and medicines used in the six months prior to starting an FDC.

Table 5 presents data on the prior treatment by the starting FDC. Only the three most common prior treatments are presented.

**Table 5: Prior treatment in the year before FDCs by starting FDC (two year lookback)**

|  | <b>Latanoprost with timolol</b> | <b>Brimonidine with timolol</b> | <b>Bimatoprost with timolol</b> | <b>Travoprost with timolol</b> | <b>Dorzolamide with timolol</b> | <b>Brinzolamide with timolol</b> | <b>Brinzolamide with brimonidine</b> |
|--|---------------------------------|---------------------------------|---------------------------------|--------------------------------|---------------------------------|----------------------------------|--------------------------------------|
| Most frequent prior medicine                 | Latanoprost (69%)               | No medicine (64%)               | Latanoprost (34%)               | Latanoprost (34%)              | No medicine (59%)               | No medicine (44%)                | Latanoprost (26%)                    |
| 2 <sup>nd</sup> most frequent prior medicine | No medicine (16%)               | Timolol (10%)                   | No medicine (21%)               | Travoprost (30%)               | Timolol (14%)                   | Timolol (17%)                    | Bimatoprost (14%) <sup>a</sup>       |
| 3 <sup>rd</sup> most frequent prior medicine | Timolol (9%)                    | Latanoprost (10%)               | Bimatoprost (21%)               | No medicine (22%)              | Latanoprost (12%)               | Latanoprost (15%)                | Brinzolamide (14%) <sup>a</sup>      |
| Total new patients (%)                       | 10,415 (32%)                    | 6,882 (21%)                     | 5,975 (19%)                     | 4,405 (14%)                    | 2,327 (7%)                      | 1,987 (6%)                       | 155 (≈0%)                            |

Source: DHS Supplied Prescriptions Database, extracted April 2016

<sup>a</sup> The same number of patients used these medicines as the last prior therapy.

For the majority of patients starting FDCs, the most common prior medicine was latanoprost. For brimonidine with timolol, dorzolamide with timolol, and brinzolamide with timolol, no prior treatment was more common than prior monotherapy.

## Analysis of expenditure

Table 6 presents the expenditure on glaucoma medicines between 2004 and 2015.

**Table 6: R/PBS expenditure on glaucoma medicines (millions)**

|                              | 2004      | 2005      | 2006      | 2007      | 2008      | 2009       | 2010       | 2011       | 2012       | 2013       | 2014      | 2015      |
|------------------------------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|------------|------------|-----------|-----------|
| Alpha agonist                | \$3.96 M  | \$3.74 M  | \$3.39 M  | \$3.25 M  | \$3.3 M   | \$3.4 M    | \$3.41 M   | \$3.56 M   | \$3.9 M    | \$4.18 M   | \$4.4 M   | \$4.74 M  |
| Beta blocker                 | \$9.47 M  | \$9.07 M  | \$7.62 M  | \$6.01 M  | \$5.07 M  | \$4.34 M   | \$3.94 M   | \$3.36 M   | \$3.01 M   | \$2.78 M   | \$2.59 M  | \$2.75 M  |
| Carbonic anhydrase inhibitor | \$2.85 M  | \$2.82 M  | \$3.07 M  | \$3.47 M  | \$4.17 M  | \$4.99 M   | \$5.47 M   | \$5.67 M   | \$6 M      | \$6.31 M   | \$7.36 M  | \$7.83 M  |
| Cholinergic                  | \$0.85 M  | \$1.02 M  | \$0.85 M  | \$0.81 M  | \$0.76 M  | \$0.67 M   | \$0.57 M   | \$0.51 M   | \$0.47 M   | \$0.44 M   | \$0.41 M  | \$0.44 M  |
| FDC                          | \$6.6 M   | \$6.74 M  | \$11.69 M | \$19.42 M | \$23.45 M | \$27.02 M  | \$31.27 M  | \$33.69 M  | \$34.68 M  | \$35.6 M   | \$37.24 M | \$37.37 M |
| Prostaglandin analogues      | \$53.22 M | \$55.06 M | \$58.07 M | \$55.73 M | \$57.24 M | \$63.81 M  | \$66.05 M  | \$65.99 M  | \$61.58 M  | \$55.96 M  | \$47.73 M | \$40.13 M |
| Total                        | \$76.95 M | \$78.45 M | \$84.71 M | \$88.68 M | \$93.98 M | \$104.22 M | \$110.71 M | \$112.77 M | \$109.64 M | \$105.26 M | \$99.73 M | \$93.27 M |

Source: DUSC database, extracted March 2016

R/PBS expenditure on glaucoma medicines grew 21% from 2004 to 2015. Prostaglandin analogues and FDCs together accounted for 83% of expenditure in 2015. Prostaglandin analogues accounted for the largest proportion of expenditure. Expenditure on prostaglandin analogues peaked in 2010 and has decreased since. Expenditure on FDCs has increased 5.7 fold between 2004 and 2015. FDCs now account for 43% of R/PBS expenditure on glaucoma medicines.

Expenditure for prostaglandin analogues and FDC products are presented at the drug level in Table 7.

**Table 7: R/PBS expenditure on prostaglandin analogues and FDCs (millions)**

|                                       | 2004      | 2005      | 2006      | 2007      | 2008      | 2009                | 2010                | 2011      | 2012      | 2013      | 2014      | 2015      |
|---------------------------------------|-----------|-----------|-----------|-----------|-----------|---------------------|---------------------|-----------|-----------|-----------|-----------|-----------|
| <b>Prostaglandin analogues</b>        |           |           |           |           |           |                     |                     |           |           |           |           |           |
| Bimatoprost                           | \$6.54 M  | \$7.24 M  | \$8.19 M  | \$8.26 M  | \$8.68 M  | \$9.75 M            | \$9.52 M            | \$9.16 M  | \$8.91 M  | \$8.66 M  | \$8.89 M  | \$8.94 M  |
| Latanoprost                           | \$43.04 M | \$44.01 M | \$45.66 M | \$43.5 M  | \$44.59 M | \$49.68 M           | \$51.66 M           | \$51.74 M | \$46.72 M | \$40.73 M | \$32.3 M  | \$25.14 M |
| Travoprost                            | \$3.63 M  | \$3.82 M  | \$4.22 M  | \$3.97 M  | \$3.97 M  | \$4.37 M            | \$4.86 M            | \$5.08 M  | \$5.94 M  | \$6.56 M  | \$6.54 M  | \$6.06 M  |
| <b>FDCs</b>                           |           |           |           |           |           |                     |                     |           |           |           |           |           |
| Bimatoprost with timolol              | -         | -         | -         | -         | -         | \$0.4 M             | \$2.35 M            | \$3.73 M  | \$4.77 M  | \$5.54 M  | \$6.42 M  | \$7.49 M  |
| Latanoprost with timolol <sup>a</sup> | \$0.44 M  | \$0.51 M  | \$4.14 M  | \$10.02 M | \$12.37 M | \$14.65 M           | \$16.24 M           | \$17.05 M | \$16.18 M | \$15.23 M | \$15.26 M | \$14.72 M |
| Travoprost with timolol               | -         | -         | \$0.03 M  | \$1.61 M  | \$3.09 M  | \$4.12 M            | \$4.88 M            | \$5.23 M  | \$5.96 M  | \$6.92 M  | \$7.53 M  | \$7.3 M   |
| Brinzolamide with timolol             | -         | -         | -         | -         | -         | -                   | \$0.1 M             | \$0.51 M  | \$0.83 M  | \$1.12 M  | \$1.4 M   | \$1.65 M  |
| Dorzolamide with timolol              | -         | -         | -         | -         | -         | ≈\$0 M <sup>b</sup> | ≈\$0 M <sup>b</sup> | \$0.01 M  | \$0.01 M  | \$0.02 M  | \$0.02 M  | \$0.02 M  |
| Brimonidine with timolol              | -         | \$0.29 M  | \$1.53 M  | \$2.16 M  | \$2.61 M  | \$2.71 M            | \$2.74 M            | \$2.66 M  | \$2.67 M  | \$2.73 M  | \$2.78 M  | \$2.9 M   |
| Pilocarpine with timolol              | \$6.16 M  | \$5.94 M  | \$5.98 M  | \$5.63 M  | \$5.38 M  | \$5.14 M            | \$4.95 M            | \$4.5 M   | \$4.25 M  | \$4.04 M  | \$3.82 M  | \$3.26 M  |
| Brinzolamide with brimonidine         | -         | -         | -         | -         | -         | -                   | -                   | -         | -         | -         | -         | \$0.02 M  |

Source: DUSC database, extracted March 2016

<sup>a</sup> Latanoprost with timolol was PBS listed in April 2006. It was listed on the R/PBS prior to this date.

<sup>b</sup> Dorzolamide with timolol was listed in March 2009. Expenditure was \$639 in 2009 and \$3,579 in 2010.

Expenditure on latanoprost peaked in 2011 and has decreased approximately 50%. Prostaglandin with timolol combination products accounted for 79% of FDC expenditure and 32% of total expenditure on glaucoma medicines. Latanoprost with timolol was the FDC with the highest R/PBS expenditure in 2015. This is followed by bimatoprost with timolol and travoprost with timolol. Pilocarpine with timolol had the largest expenditure in 2015 of FDCs that did not include a prostaglandin analogue.

## Discussion

The market for glaucoma medicines has increased slightly since 2004. The number of prescriptions supplied on the R/PBS has increased. There have been a number of changes in the medicines being used. Prostaglandin analogues continue to be the most frequently used class of medicines. The use of beta-blockers as single-ingredient preparations has decreased. The FDC products account for a substantially larger proportion of prescriptions supplied, increasing from 9% in 2004 to 30% in 2015.

Ophthalmologists prescribe the majority of prescriptions supplied on the R/PBS, followed by GPs. Optometrists have been able to prescribe glaucoma medicines on the PBS since 2009, however, only account for 1% of prescriptions supplied between 2010 and 2015. The number of prescriptions prescribed by optometrists has increased rapidly during this time. The removal of the requirement for optometrists to work in a formal shared care plan with an optometrist may increase the proportion of R/PBS prescriptions prescribed by optometrists in the future.

The analysis of prior therapies showed 33% of patients who started an FDC between July 2014 and December 2015 were not supplied a single-agent glaucoma medicine before starting an FDC. A sensitivity analysis varying the lookback time period to six months did not change the results substantially. The sensitivity analysis showed 36% of patients who started an FDC had not received a single-agent glaucoma medicine in the six months before starting an FDC. This may be a significant quality use of medicines issue if patients are starting treatment with two medicines. It is possible that some patients who appear not to have received prior treatment with a single-ingredient glaucoma medicine may have received treatment on private prescription or sample packs. However, it is likely that some patients did not have an adequate trial of a single-ingredient medicine before being supplied an FDC on the PBS. The availability of samples for newer, patented FDC medicines may be contributing to driving their uptake as a first line treatment. The PBAC has previously acknowledged the availability of samples for FDC inhalers for asthma may be driving their use as a first line maintenance therapy.<sup>27</sup>

The analysis of concession patients new to PBS glaucoma therapy showed a decreasing number of concession patients starting glaucoma medicines from 2012 onwards. This appears to be due to fewer patients starting latanoprost. It is unclear why the number of patients starting latanoprost has decreased without a commensurate increase in the number of patients starting other medicines. Generic brands for latanoprost were listed on the PBS in August 2012. The availability of cheaper generic brands may have resulted in

some concession patients opting for private prescriptions. Latanoprost promotion may also have decreased following the introduction of generic brands.

R/PBS expenditure on glaucoma medicines increased between 2004 and 2011 and has decreased thereafter. Overall expenditure peaked at \$112.77 million in 2011. Expenditure in 2015 amounted to \$93.27 million. Prostaglandin analogues and FDCs accounted for 83% of expenditure in 2015. Much of the decrease in overall expenditure has been due to the decrease in benefits paid for latanoprost. Annual expenditure on latanoprost has almost halved from \$51.74 million in 2011 to \$25.14 million in 2015 as a result of generic competition.

## **DUSC consideration**

DUSC considered that with the ageing population it might be expected that incidence of glaucoma would increase over time, and yet the number of people starting glaucoma medicines appears to be in decline. DUSC considered a shift to private prescriptions is unlikely in a mostly concessional market, and noted that there is a visible effect of the safety net in the prescription data (e.g. Figure 1 of the report). DUSC noted the availability of non-pharmacological treatments such as laser or minimally invasive glaucoma implants may have decreased reliance on pharmacological treatment for some patients; although it was noted the outcome from non-pharmacological treatment can vary and some patients may still require pharmacological treatment.

While the majority of patients who start a glaucoma medicine do so with a single ingredient medicine, DUSC noted that an increasing group of people are starting treatment with a combination product. DUSC noted a response from one sponsor that considered some patients may have been supplied monotherapy more than two years ago, and quoted a 2011 study of the PBS 10% sample.<sup>28</sup> The referenced study measured persistence on glaucoma therapy, while the current DUSC analysis did not rely on patients having persisted on therapy, but looked for any previous glaucoma prescription in the prior two years. DUSC noted sponsor responses which confirmed that sponsors provide samples of both single agent and FDC glaucoma medicines to prescribers. It is possible that some people who start PBS-subsidised treatment on an FDC may have received prior monotherapy via a sample. While the low cost of many single agent glaucoma medicines may have led to some private use of these agents, which is not visible in PBS data, DUSC reiterated that private use is likely to be small in a mostly concessional market. Commencing directly on an FDC may be clinically indicated for a small number of patients with highly elevated intraocular pressure who require rapid reduction. Despite these possible explanations, DUSC remained concerned that there may be some patients commencing on an FDC product when a single agent product would meet their needs.

Ophthalmologists prescribe the majority of glaucoma therapy prescriptions supplied on the R/PBS, followed by GPs. DUSC suggested that GPs may be more likely to continue glaucoma treatment originally prescribed by an ophthalmologist, although an analysis of initiating versus continuing prescribers was not presented in this report. DUSC noted that optometrist prescribing accounts for a small proportion of PBS prescriptions supplied for glaucoma medicines and that the pattern of optometrist prescribing in terms of medicine

class seems to reflect broader prescribing patterns. DUSC agreed with the response from one sponsor that the recent changes which permit optometrists to initiate glaucoma pharmacotherapy may present an opportunity for continuing education to ensure patients receive appropriate glaucoma treatment.

## **DUSC actions**

DUSC suggested that advice be sought from the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) and Optometry Australia seeking advice on the current treatment algorithm for glaucoma, including pharmacological and non-pharmacological treatments, changes in the surrogate outcome of intraocular pressure targets, and use of outcomes such as visual field loss.

DUSC requested that the report, sponsor responses, DUSC minutes and the advice obtained from the Royal Australian and New Zealand College of Ophthalmologists and Optometry Australia be provided to the PBAC.

## **Context for analysis**

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

## **Sponsors' comments**

Various sponsors: no comments received.

## **Disclaimer**

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health (DoH) has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

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