

Ocular lubricants: Utilisation analysis using PBS data

Drug utilisation sub-committee (DUSC)

February 2021

Abstract

Purpose

PBAC requested a review of the utilisation of ocular lubricants at its July 2020 meeting.

Data Source / methodology

Data for all ocular lubricants listed on the PBS were extracted from the Services Australia PBS supplied prescriptions database for the 7 years from January 2013 to December 2019.

Key Findings

- In 2019, there were 1.86 million ocular lubricant prescriptions dispensed on the PBS. These included 1.10 million multidose preservative containing (PC) ocular lubricant prescriptions, 445,386 single dose preservative free (PF) prescriptions and 312,139 multidose PF prescriptions.
- Since 2013, the number of ocular lubricants prescriptions dispensed on the PBS has fallen by 7.9%. This is due to a 32.7% fall in the number of prescriptions for PC formulations, largely offset by a corresponding 1573% increase in multidose PF ocular lubricant prescription numbers and a 22.0% increase in single dose PF ocular lubricant prescription numbers.
- The increase in multidose PF ocular lubricant prescription numbers is almost entirely attributable to increasing use of multidose PF sodium hyaluronate (Hylo-Fresh or Hylo-Forte). It increased 2197% from 11,831 prescriptions in 2013 to 271,709 prescriptions in 2019 and dispensing continues to grow. In contrast, the most commonly dispensed ocular lubricant in 2019 – the multidose PC ocular lubricant polyethylene glycol-400 + propylene glycol (Systane) – fell from 457,548 prescriptions in 2013 to 359,973 prescriptions in 2019.
- In 2019, the cost to government for all ocular lubricants was \$31.6 million, an increase of \$9.2 million (40.9%) when compared to expenditure on all ocular lubricants in 2013. This has been driven almost entirely by an \$8.3 million (1622%) increase in expenditure on the multidose PF ocular formulations.
- In 2019, multidose PF sodium hyaluronate accounted for 14.6% of all dispensed ocular lubricant prescriptions. Expenditure on multidose PF sodium hyaluronate alone cost

\$7.70 million, accounting for 37.1% of PBS expenditure on all PF ocular lubricants and 24.3% of PBS expenditure on all ocular lubricants.

- Approximately 80% of dispensed prescriptions for any type of ocular lubricant were prescribed by GPs. Ophthalmologists accounted for another 15.0–19.2% of prescriptions and optometrists 1.2–3.3% of prescriptions each year.
- Concessional prescriptions account for approximately 90% of all ocular lubricant prescriptions, regardless of formulation type. General (including RPBS) prescriptions accounted for 7.5% of the entire market in 2019 and 2.8% under co-payment.
- Approximately 407,000 patients had an ocular lubricant dispensed at least once in 2019. This included ~262,000 patients who were dispensed a multidose PC ocular lubricant, ~132,000 dispensed a single dose PF ocular lubricant and ~83,000 dispensed a multidose PF ocular lubricant. Patients could have had more than one type of ocular lubricant dispensed during the year.
- Between 2013 and 2019 there has been a 4.8% reduction in the number of unique patients who had an ocular lubricant dispensed. Since 2013, the number of unique patients who were dispensed a PC ocular lubricant at least once during a calendar year has decreased by 32.2% but the number of unique patients who were dispensed a single or multidose PF ocular lubricant has increased by 24.7% and 1097%, respectively.
- The majority of patients who were dispensed at least one ocular lubricant were aged 65+ years (81.8%). Two thirds of patients were women.
- The largest rises in multidose PF multidose ocular lubricant use were seen in men and women aged 65+ years. However, there has also been an 857% increase in the numbers of men aged 45–64 years and a 772% increase in the numbers of women aged 45–64 years who were dispensed a multidose PF ocular lubricant at least once over the study period.
- The number of patients started on an ocular lubricant for the first time (direct initiation) each calendar year has fallen from 165,789 in 2014 to 114,660 in 2019 (30.8% decrease). However, while the number of patients being started on a PC ocular lubricant halved over the study period, the number of patients started on a PF multidose ocular lubricant increased 508%.
- The increase in the use of PF ocular lubricants seems to be due to more patients starting on these formulations without any record of trialling a PC ocular lubricant. In 2019, ~80% of patients started on a PF ocular lubricant appear to have been directly initiated on a PF ocular lubricant. While the reason for this cannot be established using PBS data it could reflect:
 - previous use of over-the-counter or private PC or PF ocular lubricants before a patient is dispensed their first PBS prescription;
 - a clinical preference for PF ocular lubricants given difficulties in clearly classifying symptom severity, limited PBS guidance as to what constitutes severe dry eye syndrome, and guidance that states that PF formulations are preferred for patients with severe dry eye syndrome.
- While the number of patients directly started on a PF ocular lubricant is increasing, among patients started on a PC ocular lubricant, 90% have no record of being switched to a PF ocular lubricant.

Purpose of analysis

In its consideration of cationic ophthalmic emulsion at its July 2020 meeting, the PBAC noted the substantial growth in the utilisation of preservative-free ocular lubricants (eye drops). In response, the PBAC requested a review of these listings, noting the last review was completed in June 2014.

Of the 54 ocular lubricants listed on the PBS, 24 are preservative-free formulations available as authority required listings for patients sensitive to preservatives. Twelve of the 24 preservative-free authority required listings are multidose products. Figure 1 shows the rapid growth in the number of patients treated with the preservative-free formulations in the 10-year period to December 2019.

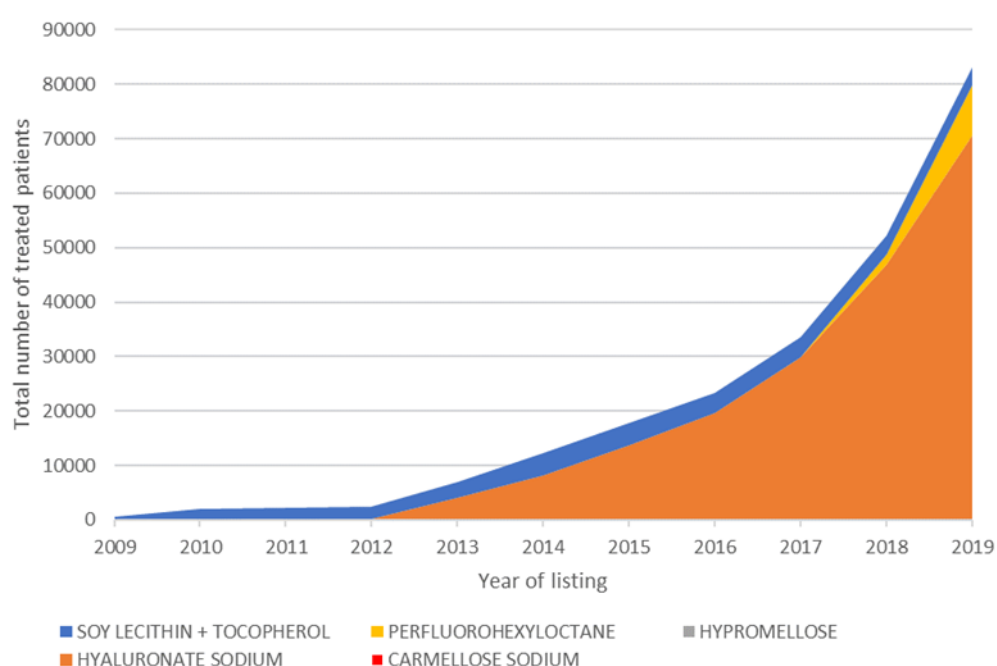


Figure 1: Number of patients treated with preservative-free ocular lubricants by PBS listing

Note: The data were extracted based on the date of supply and include the following PBS item codes: 9448G, 5545W, '02181T', 2184Y, 2253N, 2171G, 11446K, 11439C, 11852T, 11853W, 11842G and 11849P.

Source: compiled by the DUSC Secretariat based on the PBS service data

It was noted that the rising costs were driven mainly by increased uptake of hyaluronate sodium despite the authority required listing requiring a patient to be sensitive to the preservatives in multi-dose eye drops. Possible explanations suggested by the PBAC for this increase could be:

- potential use of preservative-free products without demonstrating sensitivity to products with preservatives (possibly in response to increasing patient concern about use of eye drops containing preservatives)

- reports in the literature that treatment with hyaluronate sodium results in more favourable outcomes over other preparations, including faster symptom relief and reduction in keratitis (inflammation of cornea)¹

At its June meeting, DUSC requested that the utilisation of ocular lubricants, including use of preservative free ocular lubricants, be reviewed using both PBS dispensing data and MedicineInsight data.

This paper reports on the PBS dispensing data analysis.

Background

Clinical situation

Eye health relies upon a constant flow of tears. Insufficient tear production, or problems with the mucus or oily layers of the tears, may lead to dry eye syndrome (also known as dry eye disease).

Estimates of the prevalence of dry eye symptoms and dry eye syndrome are highly variable. Population based studies that report on symptomatic disease range from 6.5% to 52.4%, with an average prevalence of $22.8 \pm 13.3\%$.² Prevalence increases with age although recent studies suggest that there is also a relatively high prevalence among younger adults and school age children – possibly due to use of digital devices.² Dry eye syndrome appears to be up to 4 times more prevalent in contact lens wearers.

There have been two Australian studies which have investigated the prevalence of dry eye symptoms and dry eye syndrome but neither are recent. In a 1998 study, the prevalence of dry eye syndrome among randomly selected Melbourne residents aged 40 years or older ranged from 1.5% to 16.3% depending on the test or symptoms used to define the condition.³ In a 1999–2001 study, the prevalence of dry eye syndrome among residents of the NSW Blue Mountains region aged 49 years or older, more than half (57.5%) reported having at least one of the dry eye symptoms and 16.6% reported at least one moderate to severe symptom. Three or more symptoms were reported by 15.3% of participants.⁴

Dry eye syndrome is a multifactorial disease of the ocular surface characterised by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and

¹ Gross D, Childs M, Piaton JM. Comparative study of 0.1% hyaluronic acid versus 0.5% carboxymethylcellulose in patients with dry eye associated with moderate keratitis or keratoconjunctivitis. Clin Ophthalmol. 2018;12:1081-8.

² Stapleton F, Alves M, Bunya VY, Jalbert I, Lekhanont K, Malet F, et al. TFOS DEWS II Epidemiology Report. Ocul Surf. 2017;15(3):334-65.

³ McCarty CA, Bansal AK, Livingston PM, Stanislavsky YL, Taylor HR. The epidemiology of dry eye in Melbourne, Australia. Ophthalmology. 1998;105(6):1114-9.

⁴ Chia EM, Mitchell P, Rochtchina E, Lee AJ, Maroun R, Wang JJ. Prevalence and associations of dry eye syndrome in an older population: the Blue Mountains Eye Study. Clin Exp Ophthalmol. 2003;31(3):229-32.

neurosensory abnormalities play aetiological roles.⁵ Symptoms of dry eye syndrome include dryness, stinging, burning, foreign-body sensation, gritty feeling, itching, and the eyes feeling heavy and tired. It may also cause paradoxical excessive tearing.

The prevalence of Sjögren syndrome is estimated to be in the order of 0.6% (0.19–1.39%).²

Women are more likely to develop dry eye syndrome than men.² Dry eye syndrome can be caused, or exacerbated by:^{6,7,8,9}

- some medicines such as antihistamines or antidepressants
- certain medical conditions such as Bell's Palsy or blepharitis/meibomian gland dysfunction
- autoimmune diseases such as lupus, Sjögren's syndrome or rheumatoid arthritis
- older age
- smoking or environmental conditions (ie, air conditioning, pollution, a dry or windy climate)
- vision correction surgery
- wearing of contact lenses.

The most common pathological causes of dry eye syndrome are meibomian gland dysfunction, Sjögren's syndrome (a systemic autoimmune disease in which immune cells attack and destroy the exocrine glands that produce tears and saliva) and non-Sjögren's lacrimal disease.⁶

There is no 'gold standard' diagnostic test for dry eye syndrome, and so a combination of signs and symptoms is commonly used as diagnostic criteria. The TFOS DEWS II report identified 17 different questionnaires that had been used to identify disease or determine disease severity of varying utility.² This uncertainty may make it difficult for clinicians to determine disease severity.

Treatment of dry eye syndrome may involve:⁶

- use of ocular lubricants – drop, gel or ointment depending on severity of symptoms.
- treatment of concurrent inflammatory skin conditions or infections
- use of warm compresses or eye masks to optimise meibomian gland function
- increasing air humidity, reducing computer use or increasing the frequency of breaks for eye rest, 'conscious blinking'.

⁵ Craig JP, Nichols KK, Akpek EK, Caffery B, Dua HS, Joo CK, et al. TFOS DEWS II Definition and Classification Report. *Ocul Surf.* 2017;15(3):276-83.

⁶ Findlay Q, Reid K. Dry eye disease: when to treat and when to refer. *Aust Prescr.* 2018;41(5):160-3.

⁷ AMH. Australian Medicines Handbook. Adelaide: Australian Medicines Handbook Pty Ltd; 2020 [accessed 15 October 2020].

⁸ Drug utilisation sub-committee (DUSC). Ocular lubricants: analysis of utilisation (June 2014). Canberra; 2014. www.pbs.gov.au/info/industry/listing/participants/public-release-docs/ocular-lubricants/ocular-lubricants

⁹ Nelson JD, Craig JP, Akpek EK, Azar DT, Belmonte C, Bron AJ, et al. TFOS DEWS II Introduction. *Ocul Surf.* 2017;15(3):269-75.

- review of medicines that may exacerbate eye symptoms (e.g. antihistamines, beta blockers, tricyclic antidepressants, selective serotonin reuptake inhibitors, isotretinoin, eye drops with preservatives).
- treatment of underlying systemic disease
- topical anti-inflammatories, ciclosporin, autologous eye drops or surgery in more severe disease.

Ocular lubricants lubricate the surface of the eye and are often referred to as artificial tears and are used to relieve the symptoms associated with dry eye syndrome.⁷

Preservatives¹⁰ are often found in eye drops, including ocular lubricants. Multidose ocular lubricants may contain a preservative or be preservative free. Single dose units are preservative free. Preservatives may irritate the corneal and conjunctival epithelium, particularly if it is already inflamed. Normally tears quickly dilute and remove preservatives; however, in dry eye syndrome (particularly when severe) reduced tear secretion may result in increased sensitivity to preservatives.⁷

The TFOS DEWS II report reviewed management options and identified that many treatments did not have a strong evidence base. There were very few randomised trials that directly compared the effectiveness of different types of ocular lubricants. As a result, and because of considerable variability in the severity and character of disease from patient to patient, the committee made management suggestions, rather than recommendations. It suggested treatment begins with commonly available therapies such as over-the-counter lubricants for mild disease (as well as education and modification diet, medicines and the local environment). However, if this is insufficient to manage disease, it recommends preservative-free (PF) ocular lubricants in order to minimise preservative induced toxicity.¹¹

This advice is echoed in Australian guidance with the Australian Medicines Handbook noting that reduced tear secretion (particularly in severe dry eye syndrome) increases risk for preservative toxicity. Preservative-free (PF) products are preferred for patients with severe dry eye syndrome; this is more important than choice of lubricant for these patients.⁷ Similarly, a recent article in Australian Prescriber noted that while preservative containing (PC) eye drops remain suitable for mild dry eye syndrome because the preservatives are diluted in the tear film, non-preserved ocular lubricants are preferred. In more severe disease, preservative-free eye drops are recommended.⁶

The recent Australian Prescriber article noted that assessment of severity is confounded by variability in clinical presentation and questionnaires are not in common use.⁶ In a 2012 survey of Australia optometrists, half reported that they assessed dry eye severity via 'clinical judgement' and the overwhelming majority never or only rarely used a standardised questionnaire to determine severity. Regardless of whether the dry eye

¹⁰ Benzalkonium chloride, polyquaternium, sodium chlorite, stabilised oxychloro complex and sodium perborate

¹¹ Jones L, Downie LE, Korb D, Benitez-Del-Castillo JM, Dana R, Deng SX, et al. TFOS DEWS II Management and Therapy Report. Ocul Surf. 2017;15(3):575-628.

syndrome was considered to be mild, moderate or severe, preservative free ocular lubricants were preferred over preservative containing ocular lubricants for treatment.^{12,13}

The PBS criteria (see below) do not provide a definition of what is considered to be severe dry eye syndrome.

Many ocular lubricants are available at low cost over the counter at pharmacies. These supplies are not captured on the PBS.

Pharmacology

Ocular lubricants lubricate the surface of the eye and are often referred to as artificial tears.

Therapeutic Goods Administration (TGA) approved indications

Ocular lubricants are registered with the TGA as class III medical devices.

Dosage and administration

Ocular lubricant eye drops are used every 1 to 12 hours on an as required basis.

The current Product Informations (PI) and Consumer Medicine Informations (CMI) are available through [the TGA website product information access page](#) and [the TGA website consumer medicines information access page](#).

PBS listing details (as at December 2020)

Streamlined

There are numerous ocular lubricant products listed on the PBS. For details of the current PBS listings refer to the PBS website.

All of the preservative-free ocular lubricants (single or multidose) are listed on the PBS as Authority required (Streamlined). To be eligible patients must have severe dry eye syndrome AND be sensitive to preservatives in multi-dose eye drops. They may be prescribed by a medical practitioner (GPs or specialists), nurse practitioners or optometrists.

Table 1 provides an overview of the PBS restrictions for preservative-free (PF) ocular lubricants.

¹² Downie LE, Keller PR, Vingrys AJ. An evidence-based analysis of Australian optometrists' dry eye practices. *Optom Vis Sci.* 2013;90(12):1385-95.

¹³ Downie LE, Rumney N, Gad A, Keller PR, Purslow C, Vingrys AJ. Comparing self-reported optometric dry eye clinical practices in Australia and the United Kingdom: is there scope for practice improvement? *Ophthalmic Physiol Opt.* 2016;36(2):140-51.

Table 1: Summarised PBS restrictions for preservative-free (PF) ocular lubricants as at December 2020

Active ingredient(s)	Brand	Authority required (streamlined) PBS code*	Optometrist authority required (streamlined) PBS code*
Single dose			
carmellose sodium	Optifresh Plus	2324H	5505R
	Optifresh Tears	2338C	5506T
	Celluvisc	8823J	5509Y
	Theratears (until Oct 2018)	8824K	05510B
carmellose sodium + glycerol (until Mar 2016)	Optive	9307W	5561Q
carbomer 974P	Poly Gel	8514D	5502N
carbomer 980	Viscotears SDU	8578L	5504Q
carbomer + triglycerides (until Apr 2015)	Artelac	2058H	2090B
hypromellose + dextran-70	Bion Tears	8299T	5521N
polyethylene glycol (until Sept 2014)	Blink Intensive Tears	9493P	5560P
polyethylene glycol-400+ propylene glycol	Systane	9170P	5532E
Multidose			
carmellose sodium (listed Dec 2019)	Evolve Carmellose	11852T	11853W
hypromellose (listed Dec 2019)	Evolve Hydromellose	11842G	11849P
sodium hyaluronate	Hylo-Forte	2181T	2171G
	Hylo-Fresh	2253N	2184Y
perfluorohexyloctane (listed Sept 2018)	Novatears	11446K	11439C
soy lecithin + tocopherol + vitamin A	tearsagain	9448G	5545W

*Severe dry eye syndrome and the patient must be sensitive to preservatives in multi-dose eye drops

All of the ocular lubricants containing preservatives listed on the PBS are multidose and can be prescribed under one of two Restricted benefit listings:

- Patients must have severe dry eye syndrome, including Sjögren's syndrome. They may be prescribed by a medical practitioner (GPs or specialists), nurse practitioners or optometrists
- Patients must have severe dry eye syndrome, including Sjögren's syndrome AND be under a GP Management Plan or Team Care Arrangements. These PBS items may only be prescribed by medical practitioners.

Table 2 provides an overview of the PBS restrictions for preservative containing (PC) ocular lubricants.

Table 2: Summarised PBS restrictions for preservative containing (PC) ocular lubricants as at December 2020

Active ingredient(s)	Brand	Restricted benefit PBS code†	Restricted benefit PBS code (requires GPMP)‡	Optometrist restricted benefit PBS code†
carmellose sodium	Refresh Tears Plus Refresh Liquigel	8548X 8593G	9211T 9212W	5507W 5508X
carmellose sodium + glycerol	Optive	9355J	9356K	5556K
hypromellose	Methopt Genteal (listed Mar 2019) In a Wink Moisturising (listed Mar 2019)	2956N 8287E (until July 2019) 11625W	9214Y 9213X (until July 2019) 11643T	5517J 5518K (until July 2019) 11634H
hypromellose + dextran-70	Poly-Tears Tears Naturale	1509K	9216C	5520M
carbomer 980	Optifresh PAA Viscotears Geltears (until Sept 2013)	8384G	9210R	5503P
carbomer + triglycerides (until Apr 2014)	Artelac	2041K	2044N	2082N
hypromellose + carbomer-980	Genteal HPMC PAA	8564R	9215B	5519L
polyethylene glycol (until Sept 2014)	Blink Intensive Tears	9491M	9492N	5559N

Active ingredient(s)	Brand	Restricted benefit PBS code†	Restricted benefit PBS code (requires GPMP)‡	Optometrist restricted benefit PBS code†
polyethylene glycol-400+ propylene glycol	Systane	8676P	9219F	5524R
polyvinyl alcohol	PVA tears Liquifilm Tears Vistil (until Apr 2019) Vistil Forte (until Apr 2019)	2682E 2681D (until March 2015) 8831T (until Apr 2019) 8832W (until Apr 2019)	9220G 9222J (until March 2015) 9221H (until Apr 2019) 9223K (until Apr 2019)	5526W 5525T (until March 2015) 5527X (until Apr 2019) 5528Y (until Apr 2019)

† Severe dry eye syndrome, including Sjögren's syndrome

‡ Severe dry eye syndrome, including Sjögren's syndrome and patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Date of listing on PBS and changes to listing

A summary of the listing dates and relevant changes to the listings of ocular lubricants from 2012 onwards can be found in Appendix A.

Current PBS listing details are available from www.pbs.gov.au

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

Ocular lubricant products have been considered by the PBAC as minor submissions and recommended on a cost minimisation basis.

Previous reviews by the DUSC

In June 2014, DUSC reviewed the utilisation of ocular lubricants. Of note, it found:

- The total number of prescriptions for ocular lubricants had been fairly steady in the ten years to 2013, increasing gradually to a peak of 2.53 million in 2009, and then slowly decreasing to 2.46 million in 2012.
- Expenditure across the whole group of ocular lubricants had been fairly stable in the last ten years to 2013. Expenditure in 2012 was \$26.2 million.
- Almost all prescriptions for ocular lubricants were over the patient co-payment (97%).
- Concessional prescriptions compile the bulk of prescriptions for ocular lubricants, with 85% of prescriptions in 2012.
- Multi-dose products account for the majority of PBS prescriptions for ocular lubricants supplied. In 2013 (until end September), 85% of prescriptions were for multi-dose products.
- Prescribing of single dose unit products was gradually increasing. Single dose unit products comprised 6.7% of prescriptions supplied 2003, 14% in 2012 and 15% in 2013

(to end September). This was considered to be the likely explanation for the gradual increase in expenditure on ocular lubricants despite stable prescription numbers.

- The most common prescribers of ocular lubricants were GPs, followed by ophthalmologists. In 2013 (to end September), approximately 72% of prescriptions supplied were prescribed by GPs and 19% by ophthalmologists. Optometrists accounted for approximately 1% of prescriptions supplied.

For details of the DUSC consideration of ocular lubricant medicines, refer to the [Public Release Document](#) from the June 2014 DUSC meeting.

Methods

The analyses used 7 years of data from the PBS supplied prescriptions database, managed by Services Australia, for dates of supply from 1 January 2013 up to and including 31 December 2019; extracted November 2020. The PBS supplied prescriptions database includes data submitted to Services Australia for payment of a PBS or Repatriation PBS (RPBS) subsidy by the Government by all approved pharmacies in Australia. These prescription data were used to determine the number of prescriptions supplied, patient category (general/RPBS, concessional or under co-payment) and for the PBS expenditure analysis.

The decision was made to restrict analysis to the period up until 31 December 2019 to avoid the COVID-19 pandemic period. However, these dates do include some of the period of the 2019–20 extreme bushfire season in which heavy smoke affected large swathes of Australia.¹⁴ Given dry eye symptoms and dry eye syndrome can be exacerbated by environmental factors, this may have increased dispensing of ocular lubricants during September to December 2019.

Prescription count analysis

Prescriptions (PBS and RPBS) for ocular lubricants dispensed between 1 January 2013 and 31 December 2019 were identified using PBS item codes as per Table 1 and Table 2.

Prescriber type was attributed to the de-identified approval number of the prescriber by Services Australia and was based on the major field of specialty, derived from the combination of the current registered specialty and the most PBS services provided per quarter. Prescribers can work in several different specialties but are allocated by Services Australia to one major field of specialty per quarter.

Patient count analysis

To be eligible for inclusion in the study, patients must have had at least one PBS or RPBS prescription for an ocular lubricant dispensed between 1 January 2013 and 31 December

¹⁴ Australian Parliamentary Library. 2019–20 Australian bushfires—frequently asked questions: a quick guide Canberra: Parliament of Australia; 2020 [updated 12 March 2020]. Available from: https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp1920/Quick_Guides/AustralianBushfires.

2019. Prevalent patients were counted by calendar years from January 2013 to December 2019. Patients initiated on an ocular lubricant (incident patients) in a calendar year were defined as patients who did not have a PBS prescription for an ocular lubricant (preservative free or preservative containing depending on the research question) supplied in any previous calendar year, starting from 1 January 2013 (this provided a minimum of twelve months prescribing history).

Data on patients started on ocular lubricants from 2014 to 2019 were further analysed according to whether the patient was:

- dispensed preservative containing ocular lubricant and had not been supplied any ocular lubricant (preservative-free or preservative containing) in at least the previous year or as long as available history allows (PC ocular lubricant direct initiation)¹⁵;
- dispensed a preservative free ocular lubricant and had not been supplied a preservative free ocular lubricant in at least the previous year or as long as available history allows (PF ocular lubricant initiation). This group may have been supplied PC ocular lubricant before initiation of the PF ocular lubricant;
- dispensed a preservative free ocular lubricant and had not been supplied any ocular lubricant (preservative-free or preservative containing) in at least the previous year or as long as available history allows (PF ocular lubricant direct initiation) – a subset of the PF ocular lubricant initiation group.

Analysis of expenditure

This analysis used information from the PBS supplied prescriptions database on the ‘benefit paid by government, less patient co-payment’ based on the published listed price. The analysis did not include any changes in the cost of other drugs.

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.¹⁶ The publicly available DHS Medicare data only includes subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included. The DHS Medicare data used in this report includes under co-payment prescriptions from 1 April 2012.

Statistical analysis

Analyses of the data were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Statistics included frequencies, proportions and measures of central tendency of numeric data as appropriate.

¹⁵ There is also a possibility that a patients may have had a preservative containing ocular lubricant dispensed (and had not been supplied any PC ocular lubricant in at least the previous year or as long as available history allows) but who have been supplied PF ocular lubricant before initiation of the PC ocular lubricant. However, this was thought to be unlikely and was not explored further.

¹⁶ PBS statistics. Australian Government Department of Human Services Medicare. Canberra. Available from <<http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp>>.

Results

Number of prescriptions supplied by formulation type

In the previous DUSC report, the total number of prescriptions for ocular lubricants was fairly steady between 2003 and 2012, increasing gradually to a peak of 2.53 million in 2009, and then slowly decreasing to 2.46 million in 2012.

In the 7 years since 2013, the number of prescriptions for ocular lubricants dispensed on the PBS has fallen by 7.9% (Figure 1 and Table 3). In 2013, 2.01 million prescriptions for ocular lubricants were dispensed on the PBS falling to 1.86 million in 2019. This has largely been driven by a 32.7% decrease in the number of prescriptions for PC formulations from 1.63 million in 2013 to 1.10 million in 2019. However, this has been somewhat offset by an increase (+1573%) in the number of PF multidose prescriptions from 18,654 prescriptions in 2013 to 312,139 in 2019. Over the same period, there has also been a 22.0% increase in the number of PF single dose formulations dispensed (from 365,113 to 445,386 prescriptions).

In 2013, 81.0% of all ocular lubricants dispensed were PC ocular lubricants but by 2019 this had decreased to 59.2% of all ocular lubricants dispensed. Of the remaining prescriptions in 2019, 24.0% were single dose PF ocular lubricants and 16.8% were PF multidose ocular lubricants (Table 3).

Note that two new PF ocular lubricants were added to the PBS in December 2019 (Evolve Carmellose and Evolve Hypromellose) and so it is possible that the number of PF multidose prescriptions may rise again in 2020.

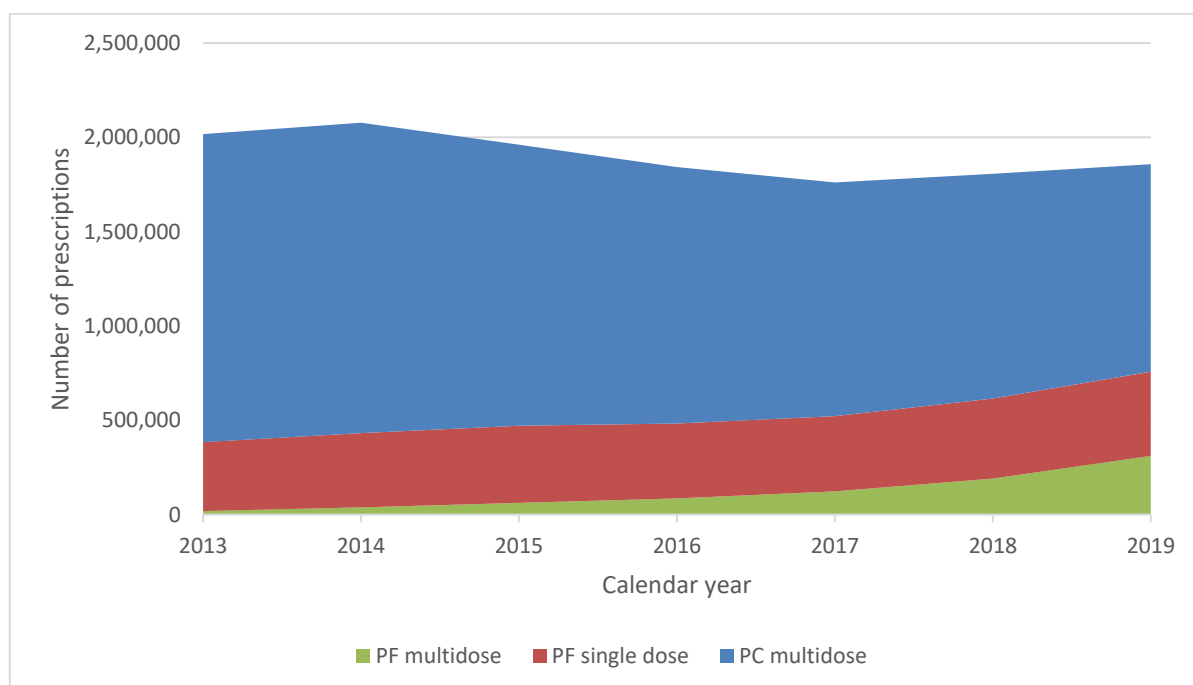


Figure 2: Number of prescriptions dispensed for ocular lubricants (cumulative total by formulation type) by calendar year 2013 to 2019

Table 3: Number of prescriptions dispensed for ocular lubricants (total and by formulation type) by calendar year

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
PF single dose	365,113 (18.1%)	392,478 (18.9%)	410,577 (20.9%)	398,442 (21.6%)	397,633 (22.6%)	424,374 (23.5%)	445,386 (24.0%)
PF multidose	18,654 (0.9%)	38,820 (1.9%)	61,274 (3.1%)	85,005 (4.6%)	123,586 (7.0%)	191,409 (10.6%)	312,139 (16.8%)
PC multidose	1,633,943 (81.0%)	1,646,657 (79.2%)	1,490,201 (76.0%)	1,359,849 (73.8%)	1,240,446 (70.4%)	1,190,974 (65.9%)	1,099,836 (59.2%)
Total	2,017,710 (100%)	2,077,955 (100%)	1,962,052 (100%)	1,843,296 (100%)	1,761,665 (100%)	1,806,757 (100%)	1,857,361 (100%)

*PC - preservative containing; PF - preservative free

All of the PC ocular formulations on the PBS are Restricted Benefits. Some of these also require that the patient must be receiving treatment under a GP Management Plan or Team Care Arrangements. Table 4 shows the breakdown of PC ocular lubricants (excluding those prescribed by an optometrist) which did or did not need to meet this requirement.

The majority of prescriptions for PC ocular lubricants are not dispensed under these arrangement (Table 4). As can be seen in Table 4 the number of prescriptions dispensed that required patients to be under these arrangements fell less steeply (10.7% decrease) than for those that did not (36.5% decrease). Due to this the proportion of OC ocular lubricants dispensed under these arrangements increased over the study period.

Table 4: Number and proportion of dispensed prescriptions of preservative containing ocular lubricants by PBS restriction type (excluding optometrist prescribing)

PBS restriction	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Does not require GPMP/TA*	1,383,294 (85.7%)	1,391,945 (85.5%)	1,235,878 (84.0%)	1,112,036 (82.7%)	996,844 (81.4%)	951,554 (81.0%)	878,156 (81.0%)
Requires GPMP/TCA†	230,485 (14.3%)	235,675 (14.5%)	236,040 (16.0%)	231,966 (17.3%)	228,284 (18.6%)	223,383 (19.0%)	205,738 (19.0%)

*1509K, 2041K, 2681D, 2682E, 2956N, 8287E, 8384G, 8548X, 8564R, 8593G, 8676P, 8831T, 8832W, 9355J, 9491M & 11625W

†2044N, 9210R, 9211T, 9212W, 9213X, 9214Y, 9215B, 9216C, 9219F, 9220G, 9221H, 9222J, 9223K, 9356K, 9492N & 11643T

Number of prescriptions supplied by active ingredient

The increase in the prescription numbers for PF ocular lubricants appears to have been driven mainly by increasing use of multidose PF sodium hyaluronate (PBS item numbers 2171G, 2181T, 2184Y & 2253N; Figure 3 and Appendix Table B1). Between 2013 and 2019, the number of prescriptions dispensed for this formulation alone increased from 11,831

prescriptions to 271,709 prescriptions (2197% increase). There is no sign that growth in the use of sodium hyaluronate is slowing down.

In 2019, multidose PF sodium hyaluronate accounted for 87% of all PF ocular lubricants, and 14.6% of all ocular lubricants, dispensed on the PBS. However, the most commonly dispensed ocular lubricant in 2019 was a PC ocular lubricant, polyethylene glycol-400+ propylene glycol (Systane). In 2019, there were 359,973 prescriptions dispensed for this formulation and it accounted for 32.7% of all PC ocular lubricants and 19.4% of all ocular lubricants (Figure 4 and Appendix Table B2).

Until 2019, the most commonly dispensed PF ocular lubricant was PF single dose carmellose (brand names: Optifresh Plus, Optifresh Tears, Celluvisc and Theratears¹⁷). The use of PF single dose hypromellose + dextran-70 (Bion Tears) has been steadily increasing since 2016.

¹⁷ Theratears was delisted in October 2018

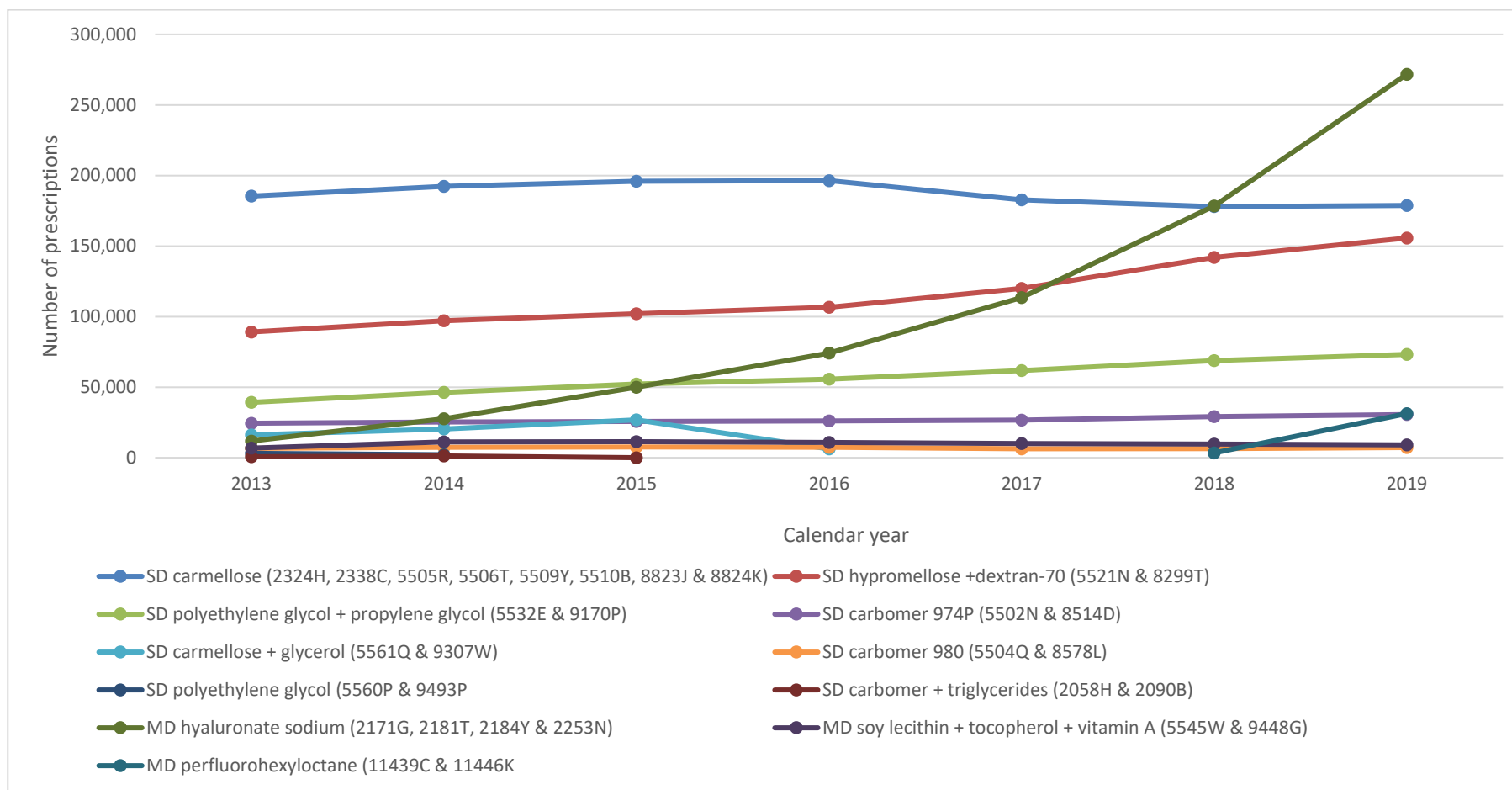


Figure 3: Total number of prescriptions dispensed for preservative free ocular lubricants (by active ingredient and whether the formulation is single dose [SD] or multidose [MD]) by calendar year 2013 to 2019.

NB: excludes MD Evolve Carmellose and MD Evolve Hypromellose which were both first listed in December 2019.

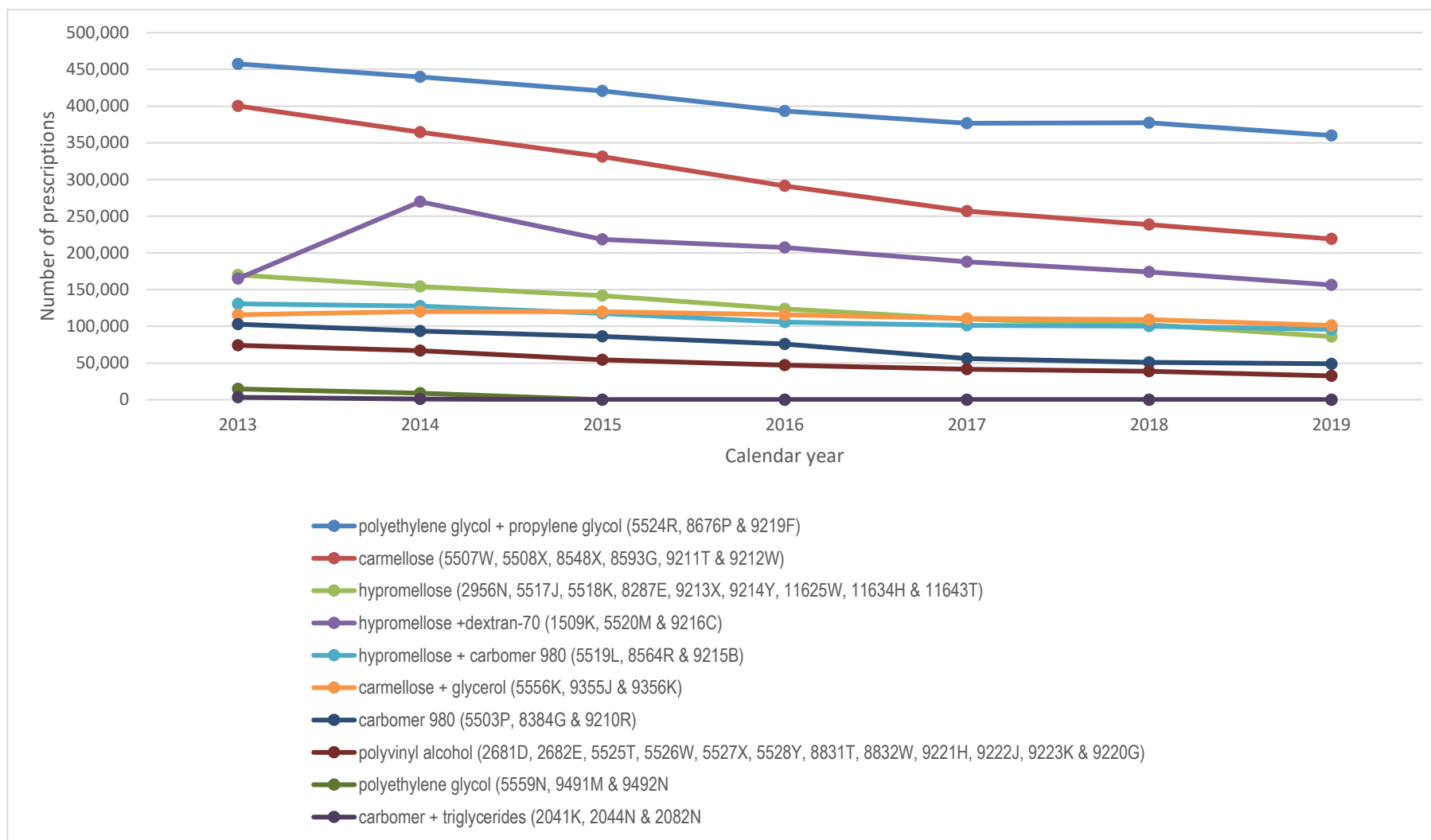


Figure 4: Total number of prescriptions dispensed for preservative containing ocular lubricants (by active ingredient) by calendar year 2013 to 2019.

Expenditure by formulation type

In 2019, the cost to government for all ocular lubricants was \$31.6 million. This was an increase of almost \$9.2 million (40.9%) over the study period. Expenditure in 2013 and 2019 for the PC ocular and the PF single dose ocular lubricant was similar but there was an \$8.3 million (1622%) increase in government expenditure on the PF multidose ocular formulations (Figure 5 and Table 5).

The dispensed price for each PF ocular lubricant as of December 2020, regardless of whether it is a multidose or single dose formulation, is approximately \$30–37 for general patients. The dispensed price for each PC ocular lubricant is approximately \$14–20.

Expenditure on the PC ocular lubricants rose in 2015 and 2016 (Figure 5) even though the number of prescriptions was falling. Despite a 16.8% decrease in the number of prescriptions for PC formulations between 2013 and 2016 (Table 3), cost to government increased from \$10.8 million in 2013 to \$13.1 million in 2016, before decreasing to \$10.9 million in 2019. It is likely that this is related to changes in pharmacy remuneration implemented as part of the Sixth Community Pharmacy Agreement (6CPA). This had the effect of increasing the dispensed price for medicines under the general co-payment, including the PC ocular lubricants by approximately \$2–5 per prescription. For several years, this increase in price appears to have offset the reduction in cost due to falling prescriptions numbers.

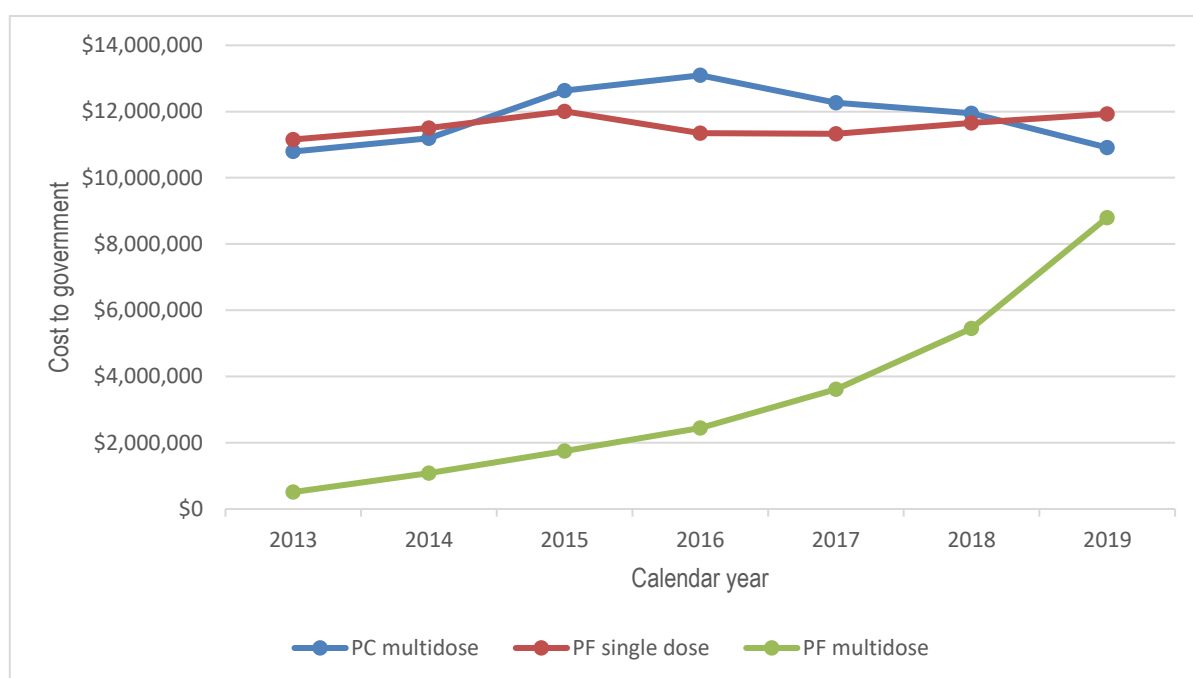


Figure 5: Cost to government for prescriptions dispensed for ocular lubricants (by formulation type) by calendar year 2013 to 2019.

Table 5: Cost to government (\$) of all dispensed prescriptions for ocular lubricants by formulation type and calendar year

Class	2013	2014	2015	2016	2017	2018	2019
PF single dose	11,156,828	11,502,147	12,007,905	11,345,435	11,330,674	11,661,126	11,929,832
PF multidose	510,937	1,083,169	1,754,336	2,446,971	3,617,365	5,455,816	8,799,312
PC multidose	10,793,444	11,191,428	12,637,954	13,094,365	12,268,626	11,947,283	10,911,634
Total	22,461,209	23,776,744	26,400,195	26,886,771	27,216,665	29,064,225	31,640,778

Expenditure by active ingredient

As can be seen in Figure 6 and Appendix Table B3, most of the expenditure on PF ocular lubricants is attributable to multidose PF sodium hyaluronate (\$7.70 million). In 2019, it accounted for 37.1% of the \$20.7 million spent on PF ocular lubricants and 24.3% of the total PBS expenditure on all ocular lubricants. The next most commonly dispensed PF ocular lubricants, PF single dose carmellose (Optifresh Plus, Optifresh Tears, Celluvisc and Theratears) and PF single dose hypromellose + dextran-70 (Bion Tears) cost \$4.15 million and \$4.83 million in 2019, respectively.

Figure 7 and Appendix Table B4 shows government expenditure on the PC ocular lubricants by active ingredient. The most costly PC ocular lubricant across all years was polyethylene glycol-400+ propylene glycol (Systane). While the total number of prescriptions for polyethylene glycol+ propylene glycol fell by 20.3% between 2013 and 2019 (Figure 4) the cost to government increased from \$3.2 million in 2013 to \$3.6 million in 2019.

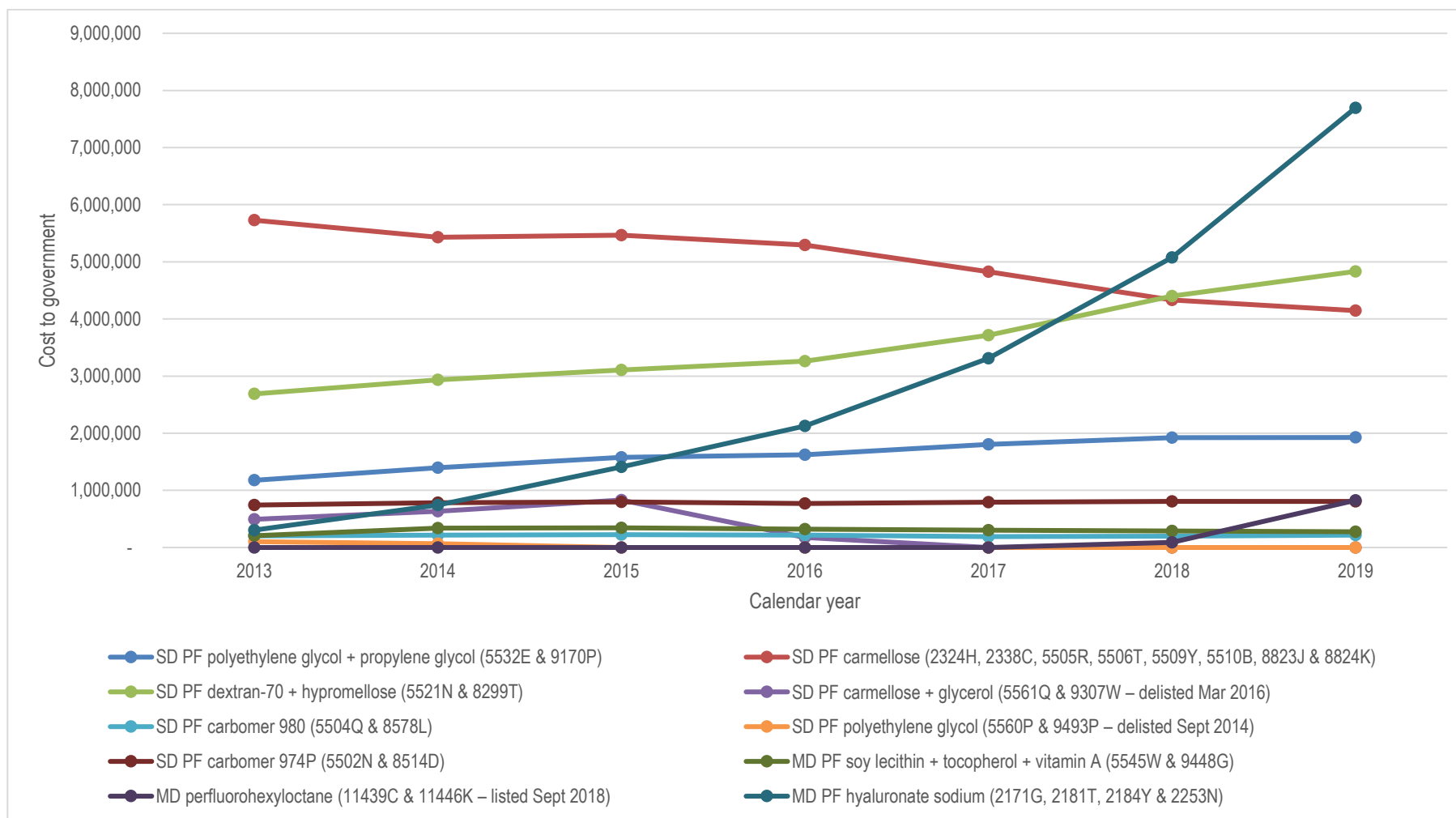


Figure 6: Cost to government for prescriptions dispensed for preservative free (PF) ocular lubricants (by active ingredient and whether the formulation is single dose [SD] or multidose [MD]) by calendar year 2013 to 2019

NB: excludes MD Evolve Carmellose and MD Evolve Hypromellose which were both first listed in December 2019.

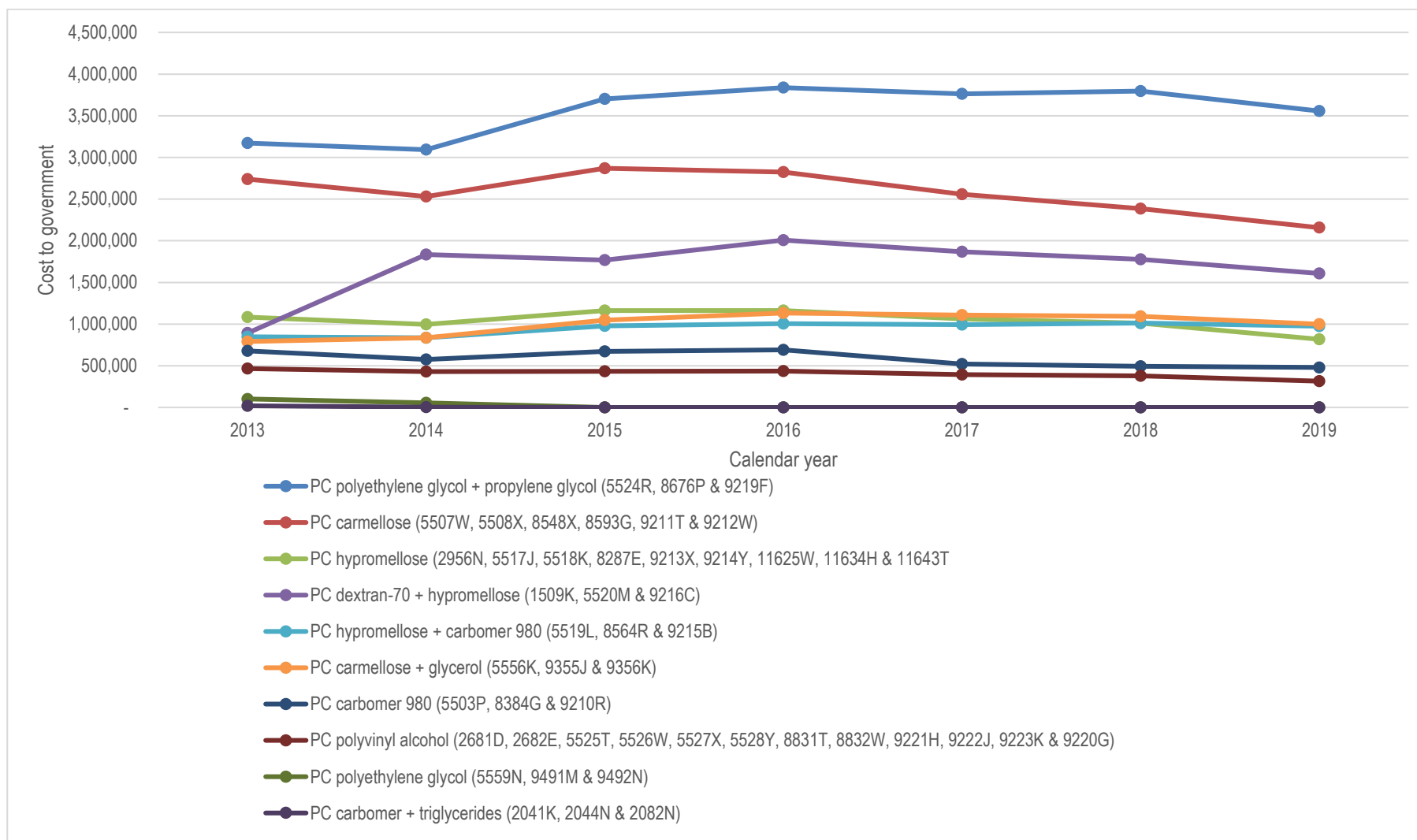


Figure 7: Cost to government for prescriptions dispensed for preservative containing (PC) ocular lubricants (by active ingredient) by calendar year 2013 to 2019

Prescriptions by prescriber type

In each year over the study period, approximately 80% of prescriptions dispensed for any type of ocular lubricant were by GPs. Ophthalmologists accounted for another 15.0–19.2% of prescriptions each year. The proportion of ocular lubricants prescribed by optometrists increased from 1.2% in 2013 to 3.3% in 2019 while prescribing by other types of specialists remained steady at around 1.2%. Nurse practitioners rarely prescribed ocular lubricants (Table 6).

Table 6: Number and proportion of dispensed prescriptions of any type of ocular lubricant by prescriber type

Prescriber	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Any ocular lubricant							
GP	1,577,178 (78.3%)	1,658,029 (79.9%)	1,574,935 (80.4%)	1,495,997 (81.3%)	1,429,375 (81.6%)	1,452,959 (80.7%)	1,453,393 (79.0%)
Ophthalmologist	386,648 (19.2%)	363,998 (17.5%)	331,434 (16.9%)	291,511 (15.8%)	262,061 (15%)	280,873 (15.6%)	301,869 (16.4%)
Optometrist	24,172 (1.2%)	24,371 (1.2%)	25,102 (1.3%)	24,933 (1.4%)	31,311 (1.8%)	42,456 (2.4%)	59,938 (3.3%)
Other specialist	26,206 (1.3%)	27,119 (1.3%)	25,650 (1.3%)	24,677 (1.3%)	23,434 (1.3%)	19,918 (1.1%)	19,994 (1.1%)
Nurse practitioner	1,271 (0.1%)	2,159 (0.1%)	2,793 (0.1%)	3,996 (0.2%)	4,685 (0.3%)	4,689 (0.3%)	4,714 (0.3%)
Total	2,015,475 (100%)	2,075,676 (100%)	1,959,914 (100%)	1,841,114 (100%)	1,750,866 (100%)	1,800,895 (100%)	1,839,908 (100%)

In 2019, GPs prescribed 337,341 of the single dose PF ocular lubricant (76.6%), 181,196 (58.4%) of the multidose PF ocular lubricant and 934,856 (85.8%) of the PC ocular lubricant prescriptions dispensed (Figure 8 and Table 6).

While the number of any ocular lubricants that were supplied by GPs fell from 1.58 million prescriptions in 2013 to 1.45 million in 2019, the total number of prescriptions supplied by GPs that were either single dose or multidose PF ocular lubricants increased (Figure 8 and Table 7). In contrast the total number of PC ocular lubricant prescriptions supplied by GPs fell from 1.30 million in 2013 to 934,856 in 2019 (28.2% decrease).

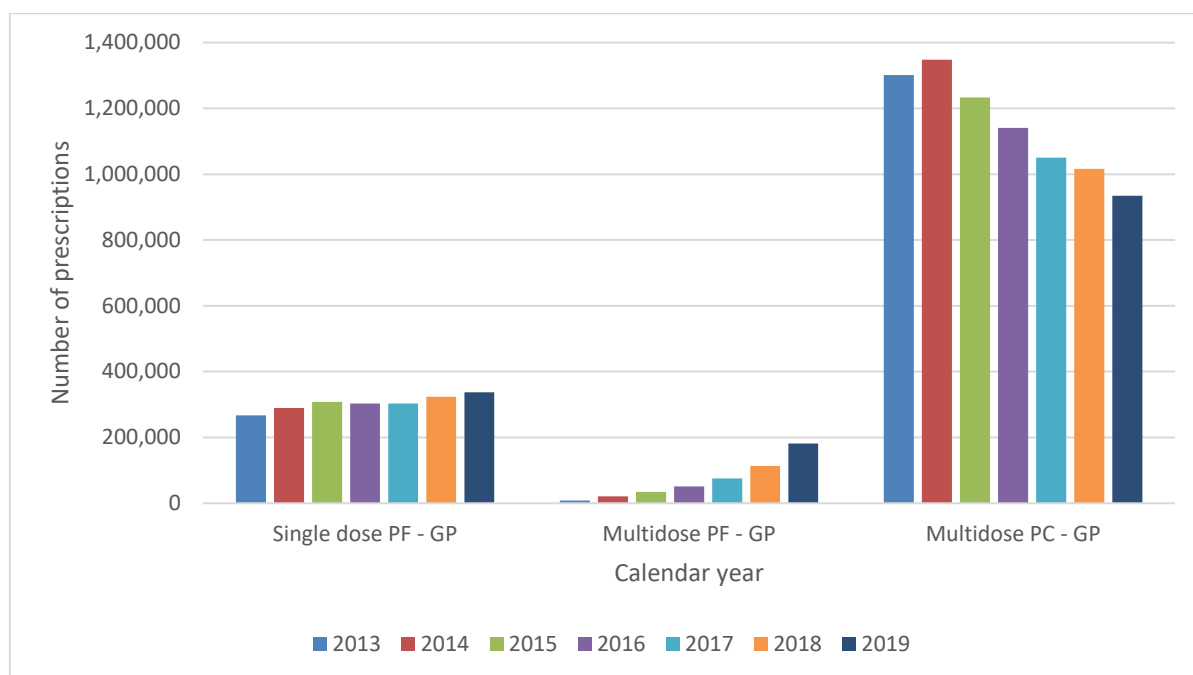


Figure 8: Number of single dose or multidose preservative free (PF) or multidose preservative containing (PC) ocular lubricant prescriptions dispensed that were supplied by GPs by calendar year 2013 to 2019.

Table 7: Number and proportion of dispensed prescriptions of ocular lubricant by type of formulation and prescriber

Prescriber	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Preservative free single dose							
GP	266,706 (73.1%)	289,781 (73.9%)	307,783 (75%)	303,648 (76.3%)	303,325 (76.7%)	323,552 (76.5%)	337,341 (76.6%)
Ophthalmologist	88,924 (24.4%)	91,789 (23.4%)	90,990 (22.2%)	82,939 (20.8%)	78,067 (19.7%)	84,250 (19.9%)	85,193 (19.3%)
Optometrist	3,658 (1%)	4,499 (1.1%)	5,033 (1.2%)	5,554 (1.4%)	8,174 (2.1%)	10,328 (2.4%)	12,226 (2.8%)
Specialist	5,249 (1.4%)	5,780 (1.5%)	5,998 (1.5%)	5,554 (1.4%)	5,327 (1.3%)	4,654 (1.1%)	5,057 (1.1%)
Nurse practitioner	176 (0.0%)	200 (0.1%)	362 (0.1%)	361 (0.1%)	406 (0.1%)	392 (0.1%)	468 (0.1%)
Preservative free multidose							
GP	8,746 (46.9%)	20,624 (53.2%)	34,261 (56%)	51,203 (60.3%)	75,861 (61.7%)	113,092 (59.2%)	181,196 (58.4%)
Ophthalmologist	9,380 (50.3%)	16,935 (43.7%)	24,493 (40%)	29,097 (34.3%)	37,521 (30.5%)	59,791 (31.3%)	94,187 (30.4%)

Prescriber	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Optometrist	318 (1.7%)	801 (2.1%)	1,765 (2.9%)	3,515 (4.1%)	7,892 (6.4%)	16,099 (8.4%)	31,785 (10.2%)
Specialist	189 (1%)	412 (1.1%)	651 (1.1%)	1,011 (1.2%)	1,406 (1.1%)	1,837 (1%)	2,729 (0.9%)
Nurse practitioner	5 (0%)	9 (0%)	29 (0%)	102 (0.1%)	219 (0.2%)	233 (0.1%)	418 (0.1%)
Preservative containing multidose							
GP	1,301,726 (79.8%)	1,347,624 (81.9%)	1,232,891 (82.8%)	1,141,146 (84%)	1,050,189 (85.2%)	1,016,315 (85.6%)	934,856 (85.8%)
Ophthalmologist	288,344 (17.7%)	255,274 (15.5%)	215,951 (14.5%)	179,475 (13.2%)	146,473 (11.9%)	136,832 (11.5%)	122,489 (11.2%)
Optometrist	20,196 (1.2%)	19,071 (1.2%)	18,304 (1.2%)	15,864 (1.2%)	15,245 (1.2%)	16,029 (1.4%)	15,927 (1.5%)
Specialist	20,768 (1.3%)	20,927 (1.3%)	19,001 (1.3%)	18,112 (1.3%)	16,701 (1.4%)	13,427 (1.1%)	12,208 (1.1%)
Nurse practitioner	1,090 (0.1%)	1,950 (0.1%)	2,402 (0.2%)	3,533 (0.3%)	4,060 (0.3%)	4,064 (0.3%)	3,828 (0.4%)

The number of multidose PF ocular lubricants prescriptions supplied by ophthalmologists and optometrists also increased over the study period (Figure 9 and Table 8).

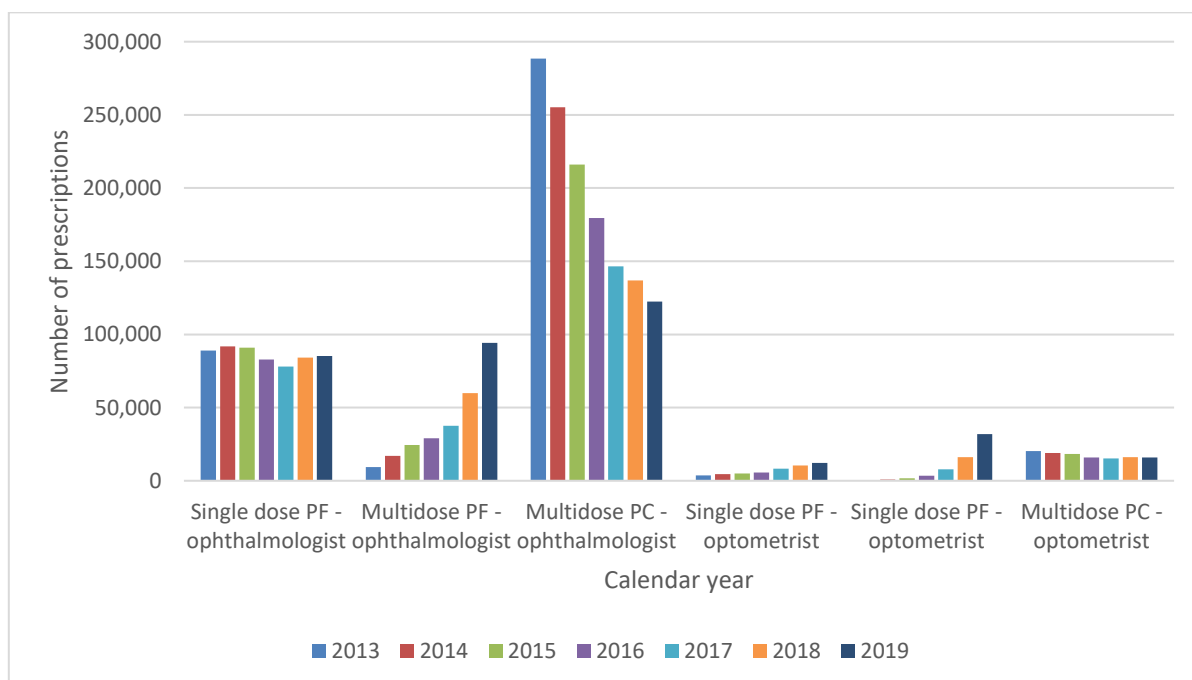


Figure 9: Number of ocular lubricant prescriptions dispensed that were supplied by GPs, ophthalmologists and optometrists by calendar year 2013 to 2019.

Prescriptions by patient status

The bulk of prescriptions for ocular lubricants was for concessional patients, with 1.66 million of all 1.86 million (89.6%) prescriptions in 2019, as illustrated in Figure 10. General (including RPBS) prescriptions accounted for 7.5% of the market with 139,979 prescriptions dispensed in 2019.

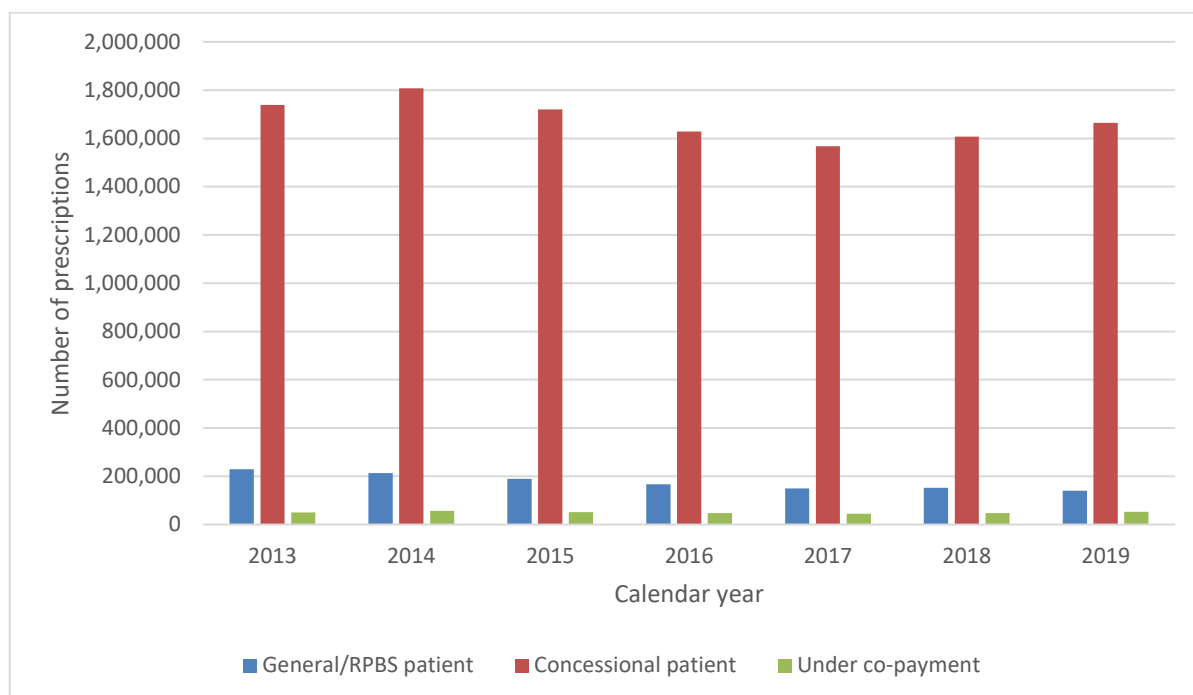


Figure 10: Number of prescriptions for any ocular lubricant per year by patient category

There was a small rise in the proportion of ocular lubricants that were concessional prescriptions, from 86.2% of prescriptions in 2013 to 89.6% in 2019 (Table 8). There was a corresponding drop – from 11.4% on 2013 to 7.5% in 2019 – in the proportion of prescriptions that are general or RPBS prescriptions.

The proportion of prescriptions under co-payment was stable over the study period and accounted for 2.4–2.8% of the market in all years. Many of the ocular lubricants can be purchased over the counter and, for non-concessional patients, it may have been cheaper to buy over the counter than on prescription. In December 2019, the dispensed prices for PF ocular lubricants and PC ocular lubricants were approximately \$30–37 and \$14–20, respectively which was lower than the \$40.30 general patient co-payment.¹⁸

¹⁸ Schedule of Pharmaceutical Benefits (effective 1 December 2019).

www.pbs.gov.au/publication/schedule/2019/12/2019-12-01-general-schedule-volume-1.pdf

Table 8: Number and proportion of dispensed prescriptions of any ocular lubricant by patient status

Prescriber	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Any ocular lubricant							
General/RPBS patient	229,496 (11.4%)	212,754 (10.2%)	189,855 (9.7%)	166,983 (9.1%)	149,263 (8.5%)	152,004 (8.4%)	139,979 (7.5%)
Concessional patient	1,738,797 (86.2%)	1,808,338 (87%)	1,720,372 (87.7%)	1,628,915 (88.4%)	1,567,789 (89.0%)	1,607,703 (89.0%)	1,664,869 (89.6%)
Under co-payment	49,417 (2.4%)	56,863 (2.7%)	51,825 (2.6%)	47,398 (2.6%)	44,613 (2.5%)	47,050 (2.6%)	52,513 (2.8%)
Total	2,017,710 (100%)	2,077,955 (100%)	1,962,052 (100%)	1,843,296 (100%)	1,761,665 (100%)	1,806,757 (100%)	1,857,361 (100%)

Over the study period, the proportion of prescriptions supplied to concessional patients has increased over the years for both single dose and multidose PF ocular lubricants (Appendix Table B5). In 2013, concessional patients accounted for 84.9% of all single PF ocular lubricant prescriptions dispensed and 77.4% of all multidose PF ocular lubricant prescriptions dispensed. In 2019, these proportions had increased to 90.8% and 89.2%, respectively. Concessional patients also accounted for 87–89% of all PC ocular lubricants dispensed in each calendar year.

Sodium hyaluronate prescriptions

In 2013 there were 11,831 prescriptions for multidose PF sodium hyaluronate dispensed on the PBS. By 2019, this had increased to 271,709 prescriptions (2197% increase) and there is no sign that the growth in sodium hyaluronate is slowing.

In 2013, the majority of prescriptions for PF sodium hyaluronate dispensed were by ophthalmologists (61.2%). However, from 2015 onwards, GPs were the most common prescribers (Figure 11). In 2019, 60.4% of prescriptions (163,044 prescriptions) dispensed were prescribed by GPs, followed by ophthalmologists (29.3%, 79,163 prescriptions).

The proportion of PF sodium hyaluronate dispensed which was prescribed by optometrists rose over the study period from 208 prescriptions (1.2% of all dispensed prescriptions) in 2013 to 24,958 prescriptions in 2019 (9.2%). Nurse practitioners and other specialists rarely prescribed PF sodium hyaluronate (Figure 11).

In 2019, the majority (89.6%) of sodium hyaluronate prescriptions were dispensed to concessional patients. Another 7.1% were dispensed to general patients and 3.3% were under co-payment.

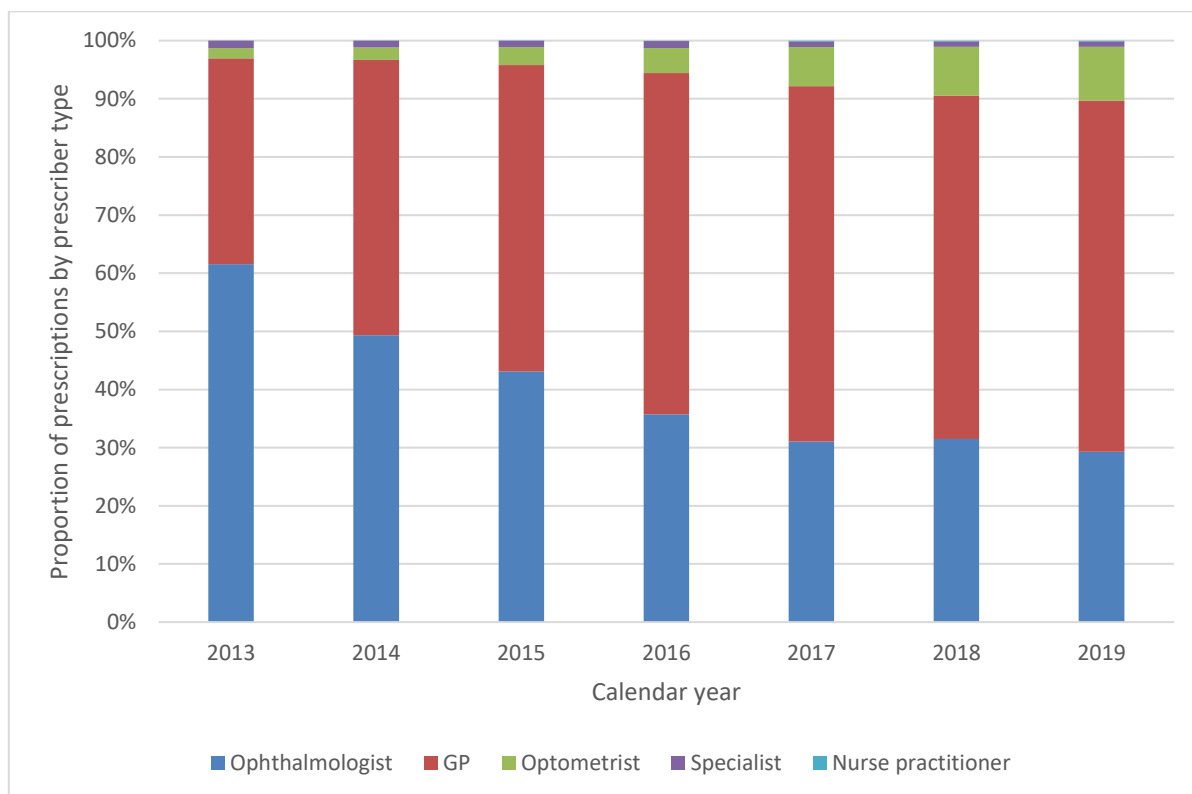


Figure 11: Proportion of sodium hyaluronate prescriptions dispensed by prescriber type

Number of prescriptions flagged with an aged care identifier (exploratory analysis)

As of 1 July 2020, all PBS claims for residents who live in a residential aged care facility (RACF) must be clearly identified and include the unique four-digit identification number that corresponds to the RACF in which they live. While this aged care identifier only became mandatory in 2020, some software vendors began introducing this identifier in 2019.

Investigation of the field in 2019 PBS data showed that this field was blank for 87.8% of prescriptions. Approximately 3% of prescriptions included a 1–3 numerical code (0-999) and 10% a four-digit code (1000-9999). Table 9 shows the proportion of ocular lubricants dispensed in 2019 which was identified as being dispensed to a resident of an RACF. However, this analysis assumes that any non-zero code indicates that the patient to whom the script was dispensed resides in an RACF and that any blank or zero code indicates that the patient was not residing in an RACF. These assumptions are likely to be unreliable and so these estimates should be treated with extreme caution.

Given these cautions, it does appear PC multidose ocular formulations are more likely to be prescribed to residents of RACFs than patients who have not been identified as living within an RACF (Table 9).

Table 9: Number and proportion of dispensed prescriptions of ocular lubricant in 2019 with an aged care identifier

Class	Aged care identifier No. (%)	No aged care identifier No. (%)
PF single dose	24,551 (10.9%)	420,835 (25.8%)
PF multidose	10,392 (4.6%)	301,747 (18.5%)
PC multidose	190,938 (84.5%)	908,898 (55.7%)
Any	225,881 (100%)	1,631,480 (100%)

Number of patients prescribed an ocular lubricant by formulation type

Over the entire 7-year study period there were 1,171,348 unique patients who had an ocular lubricant dispensed at least once. In 2019, there were 261,690 patients who were dispensed an PC ocular lubricant at least once, 131,680 dispensed a single dose PF ocular lubricant and 83,037 dispensed a multidose PF ocular lubricant (Figure 12 and Table 10).

In the 7 years since 2013, the number of unique patients dispensed a PC ocular lubricant at least once during a calendar year has fallen (32.2% decrease; Figure 12 and Table 10). In contrast the number of unique patients dispensed a single or multidose PF ocular lubricant has increased by 24.7% and 1097%, respectively.

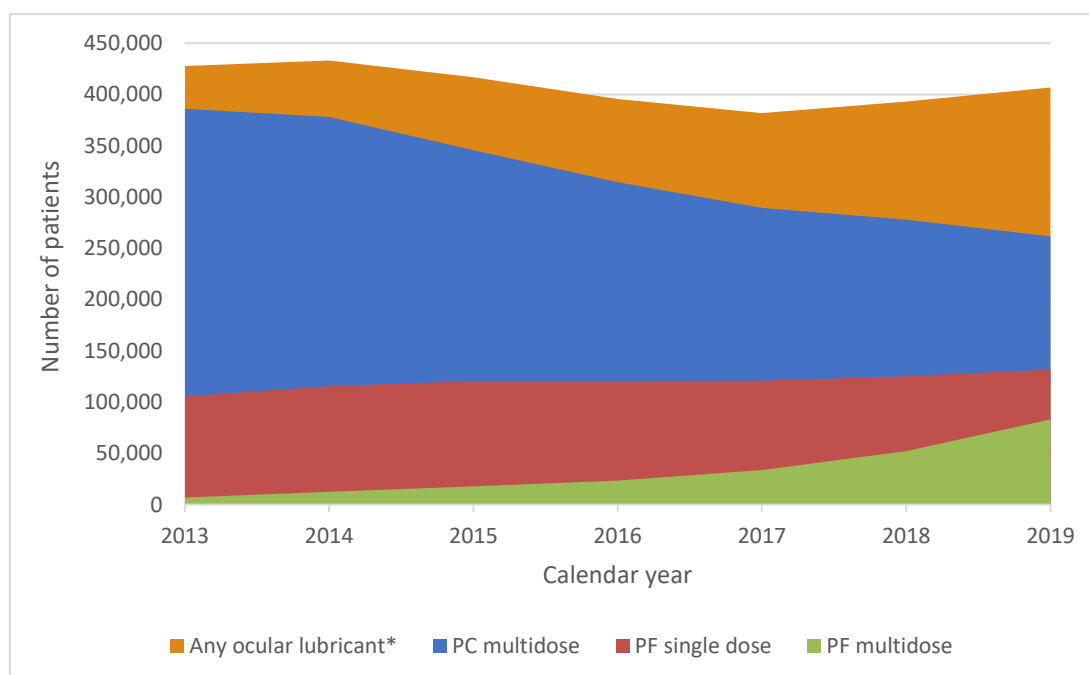


Figure 12: Number of unique patients* who were dispensed an ocular lubricant at least once between January 2013 and December 2019, by formulation type

*Patients may have been dispensed more than one type of ocular lubricant in a calendar year

Table 10: Number of unique patients* who were dispensed prescriptions of any ocular lubricant by formulation type and calendar year

Class	2013	2014	2015	2016	2017	2018	2019
PF single dose	105,608	115,598	120,610	120,606	120,670	125,216	131,680
PF multidose	6,939	12,340	17,791	23,373	33,549	52,143	83,037
PC multidose	385,966	378,145	345,602	314,420	289,223	277,740	261,690
Total†	427,526	433,079	416,797	395,367	381,671	392,997	406,905

*Note that patients may have been dispensed more than one type of ocular lubricant in a calendar year

†The number of unique patients prescribed at least one PF or PC ocular lubricant

Similar trends to those seen in the analysis of number of prescriptions dispensed for ocular lubricants by active ingredient were seen in the patient level analysis (Appendix Tables B4 and B5). The largest increase was among patients dispensed multidose PF sodium hyaluronate (PBS item numbers 2171G, 2181T, 2184Y & 2253N). Between 2013 and 2019, the number of patients dispensed sodium hyaluronate at least once increased from 4138 patients to 70,557 patients (1605% increase). The only ocular lubricant that was dispensed to more patients in 2019 was PC polyethylene glycol-400 + propylene glycol (Systane; PBS item numbers 5524R, 8676P & 9219F) which was dispensed at least once to 84,233 patients (a drop of approximately 21,000 patients since 2013).

Among the other PF ocular lubricants, there was also an increase in the number of patients prescribed PF single dose dextran-70 + hypromellose (Bion Tears; 5521N & 8299T) from 23,643 in 2013 to 41,717 in 2019. Multidose PF perfluorohexyloctane (Novatears; 11439C & 11446K) was listed in 2018 and dispensed to 9302 patients at least once in 2019. Evolve Carmellose and Evolve Hypromellose which were only listed in December 2019, were dispensed to 10 and fewer than 5 patients, respectively.

The number of patients dispensed the various PC ocular lubricants fell for all active ingredients.

Demographics of patients dispensed an ocular lubricant

Any ocular lubricant

Over the 7-year period, the number of unique patients dispensed an ocular lubricant of any kind has hovered around the 400,000 mark (Figure 13; Table 11). The year in which the most patients were dispensed an ocular lubricant was 2014 with 433,079 patients and the year with the least patients dispensed an ocular lubricant was 2017 (381,671 patients).

Consistent with the high proportion of prescriptions that are dispensed to concessional patients, the majority of patients dispensed at least one ocular lubricant were aged 65+ years (81.8%). Two thirds were women (Table 10).

The largest group of patients dispensed an ocular lubricant are females aged 65+ years (Figure 9; Table 15). Females aged 65+ years accounted for approximately 55% of all unique patients dispensed an ocular lubricant each year. Males aged 65+ years were the second highest users accounting for another 26–27% of patients dispensed an ocular lubricant each year. There have been no substantial changes within age groups or sexes over the study period.

Note that there were 147 patients who were missing either age or sex in the dataset and these patients have been excluded from this analysis.

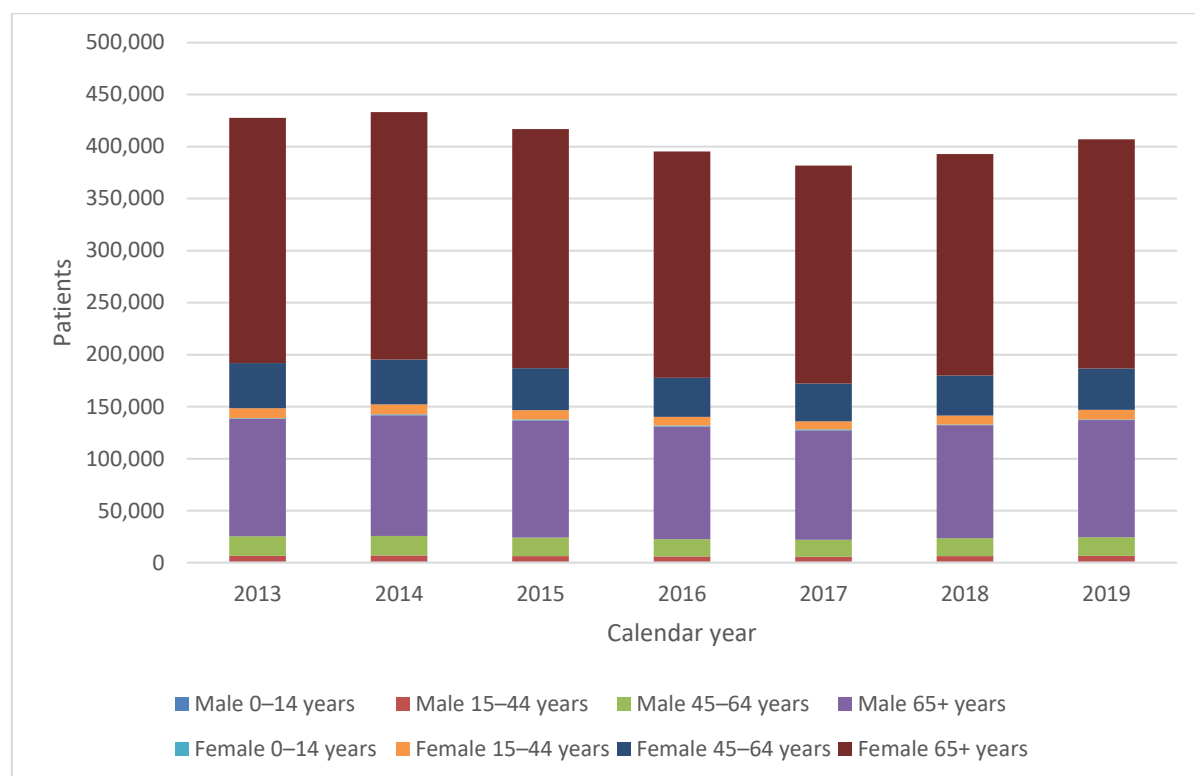


Figure 13: Number of unique patients* who were dispensed an ocular lubricant at least once between January 2013 and December 2019, by age-sex groups

*147 patients who had no records of sex and/or age were excluded from this analysis

Tables 11: Number of patients* who were dispensed prescriptions of any ocular lubricants by age, sex, age-sex and calendar year

Characteristic	2013 N (%)	2014 N (%)	2015 N (%)	2016 N (%)	2017 N (%)	2018 N (%)	2019 N (%)
Total	427,526	433,079	416,797	395,367	381,671	392,997	406,905
Sex							
Male	138,242 (32.3%)	141,778 (32.7%)	136,767 (32.8%)	130,973 (33.1%)	127,224 (33.3%)	132,053 (33.6%)	136,952 (33.7%)
Female	289,284 (67.7%)	291,301 (67.3%)	280,030 (67.2%)	264,394 (66.9%)	254,447 (66.7%)	260,944 (66.4%)	269,953 (66.3%)
Age							

Characteristic	2013 N (%)	2014 N (%)	2015 N (%)	2016 N (%)	2017 N (%)	2018 N (%)	2019 N (%)
0–14 years	1,885 (0.4%)	2,009 (0.5%)	1,966 (0.5%)	1,909 (0.5%)	1,889 (0.5%)	2,026 (0.5%)	1,968 (0.5%)
15–44 years	14,826 (3.5%)	15,222 (3.5%)	14,243 (3.4%)	13,337 (3.4%)	12,600 (3.3%)	13,720 (3.5%)	14,482 (3.6%)
45–64 years	62,282 (14.6%)	61,873 (14.3%)	58,182 (14%)	54,097 (13.7%)	52,452 (13.7%)	55,392 (14.1%)	57,763 (14.2%)
65+ years	348,533 (81.5%)	353,975 (81.7%)	342,406 (82.2%)	326,024 (82.5%)	314,730 (82.5%)	321,859 (81.9%)	332,692 (81.8%)
Age-sex							
Male 0–14 years	1,054 (0.2%)	1,152 (0.3%)	1,124 (0.3%)	1,067 (0.3%)	1,048 (0.3%)	1,164 (0.3%)	1,087 (0.3%)
Male 15–44 years	5,396 (1.3%)	5,618 (1.3%)	5,205 (1.2%)	5,035 (1.3%)	4,728 (1.2%)	5,139 (1.3%)	5,406 (1.3%)
Male 45–64 years	18,872 (4.4%)	18,977 (4.4%)	17,793 (4.3%)	16,569 (4.2%)	16,117 (4.2%)	17,149 (4.4%)	17,977 (4.4%)
Male 65+ years	112,920 (26.4%)	116,031 (26.8%)	112,645 (27%)	108,302 (27.4%)	105,331 (27.6%)	108,601 (27.6%)	112,482 (27.6%)
Female 0–14 years	831 (0.2%)	857 (0.2%)	842 (0.2%)	842 (0.2%)	841 (0.2%)	862 (0.2%)	881 (0.2%)
Female 15–44 years	9,430 (2.2%)	9,604 (2.2%)	9,038 (2.2%)	8,302 (2.1%)	7,872 (2.1%)	8,581 (2.2%)	9,076 (2.2%)
Female 45–64 years	43,410 (10.2%)	42,896 (9.9%)	40,389 (9.7%)	37,528 (9.5%)	36,335 (9.5%)	38,243 (9.7%)	39,786 (9.8%)
Female 65+ years	235,613 (55.1%)	237,944 (54.9%)	229,761 (55.1%)	217,722 (55.1%)	209,399 (54.9%)	213,258 (54.3%)	220,210 (54.1%)

*147 patients who had no records of sex and/or age were excluded from this analysis

Ocular lubricants by formulation type

Over the 7 year study period the number of unique patients dispensed a single dose PF ocular lubricant increased from 105,601 to 131,678 (24.7% increase; Figure 14 and Appendix Table B1). This was due to increased use among patients aged 65+ years. Among men aged 65+ years, use of PF single dose ocular lubricants rose from 21,728 patients in 2013 to 31,188 patients in 2019 (43.5% increase). In women aged 65+ years the corresponding patient numbers were 58,157 in 2013 and 74,073 in 2019 (27.4% increase).

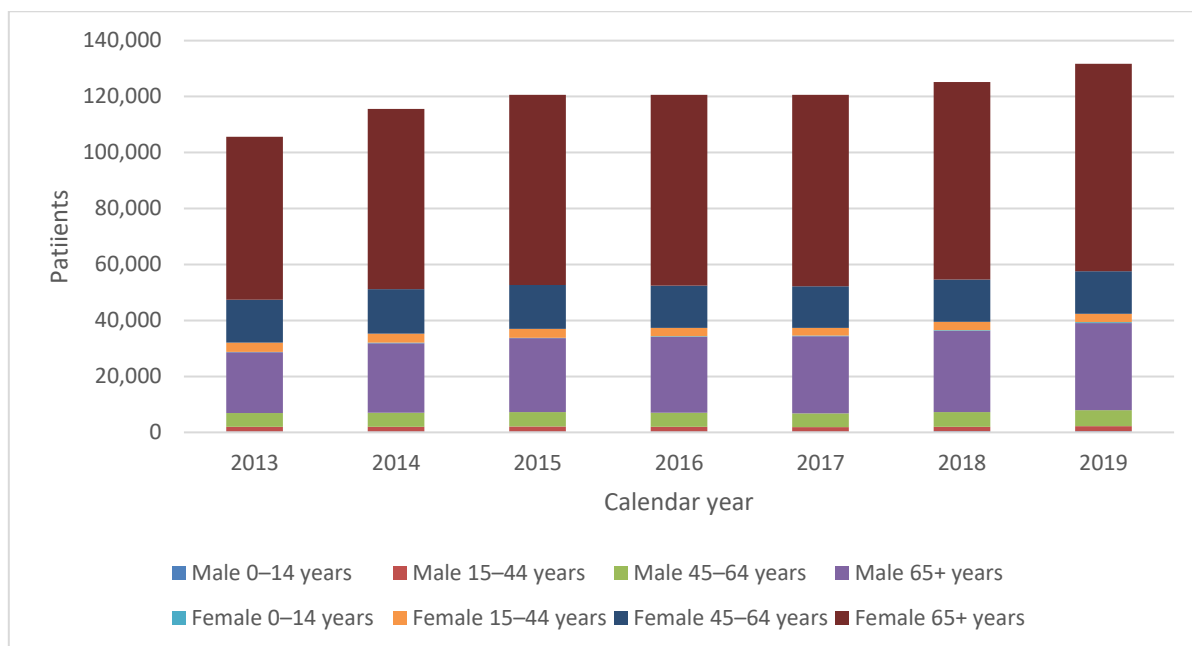


Figure 14: Number of unique patients who were dispensed a preservative free (PF) single dose ocular lubricant at least once between January 2013 and December 2019, by age-sex groups

Over the 7 year study period the number of unique patients dispensed a PF multidose ocular lubricant increased from 6938 patients to 83,035 patients (1096% increase; Figure 15 and Appendix Table B2). There has been increasing use in all age groups and sexes but the increases have largely been driven by increasing use among:

- men aged 45–64 years from 370 patients in 2013 to 3542 patients in 2019 (857% increase)
- women aged 45–64 years from 1196 to 10,434 (772% increase)
- men aged 65+ years from 1398 to 20,269 (1350% increase)
- women aged 65+ years from 3535 to 44,933 (1171% increase).

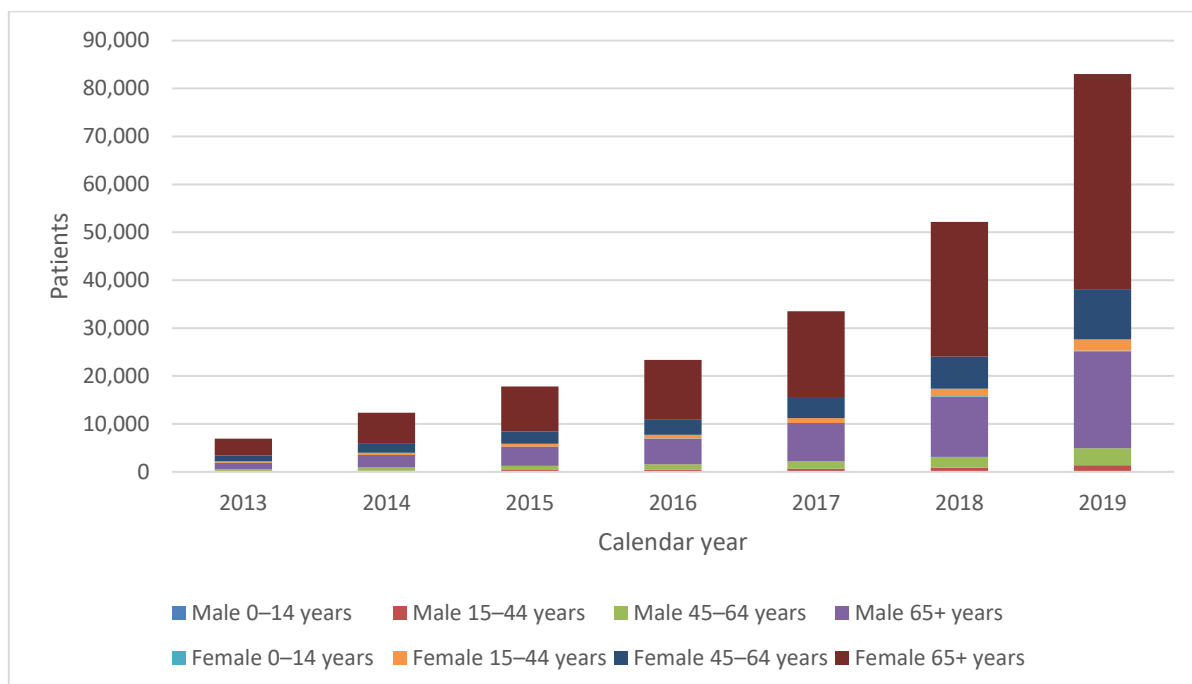


Figure 15: Number of unique patients who were dispensed a preservative free (PF) multidose ocular lubricant at least once between January 2013 and December 2019, by age-sex groups

Over the 7 year study period the number of unique patients dispensed a PC multidose ocular lubricant fell from 385,904 patients to 261,675 patients (32.2% decrease; Figure 16 and Appendix Table B3). There has been decreasing use in all age groups and sexes but the decrease has largely been driven by falls in use among patients aged 65+ years. Among men aged 65+ years, use of PC multidose ocular lubricants fell from 107,012 patients in 2013 to 78,653 patients in 2019 (26.5% decrease). In women aged 65% the corresponding patient numbers were 217,077 in 2013 and 143,144 in 2019 (34.1% decrease).

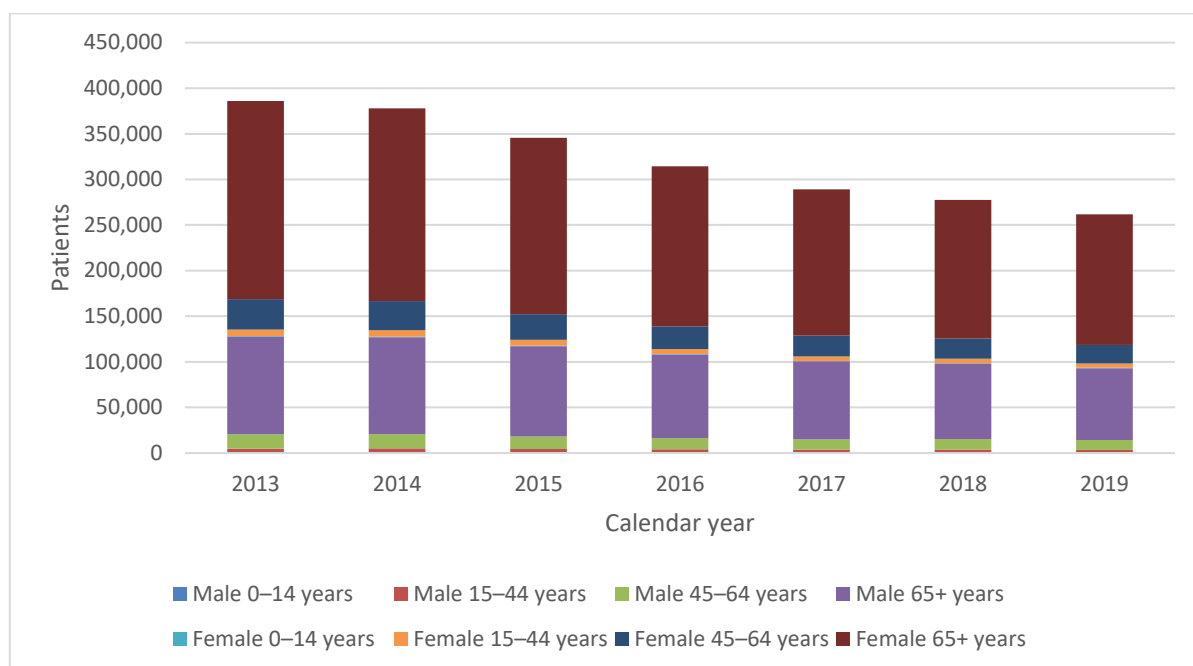


Figure 16: Number of unique patients who were dispensed a preservative containing (PC) multidose ocular lubricant at least once between January 2013 and December 2019, by age-sex groups

Initiation of ocular lubricants

Patients directly started on an ocular lubricant each calendar year between 2014 and 2019 were defined as patients who did not have a PBS prescription for any ocular lubricant supplied in any previous calendar year, starting from 1 January 2013 (this provided a minimum of twelve months prescribing history).

The number of patients started on an ocular lubricant for the first time (direct initiation) has fallen from 165,789 in 2014 to 114,660 in 2019 (30.8% decrease). This is due to a halving of the number of patients being started on a PC ocular lubricant (Figure 17 and Table 12). In contrast, the number of patients started on PF multidose ocular lubricants has increased 508% from 4,203 patients in 2014 to 25,579 in 2019. The number of patients started on a single dose PF ocular lubricant has fallen from 2014 (22.2% decrease) but has remained steady at approximately 25,000 patients in recent years.

Over the study period there were 4,292 patients (0.4% of all patients dispensed an ocular lubricant at least once over the study period) who were dispensed both a PC ocular formulation and a PF ocular formulation on the same day. These patients have not been included in analyses of initiation.

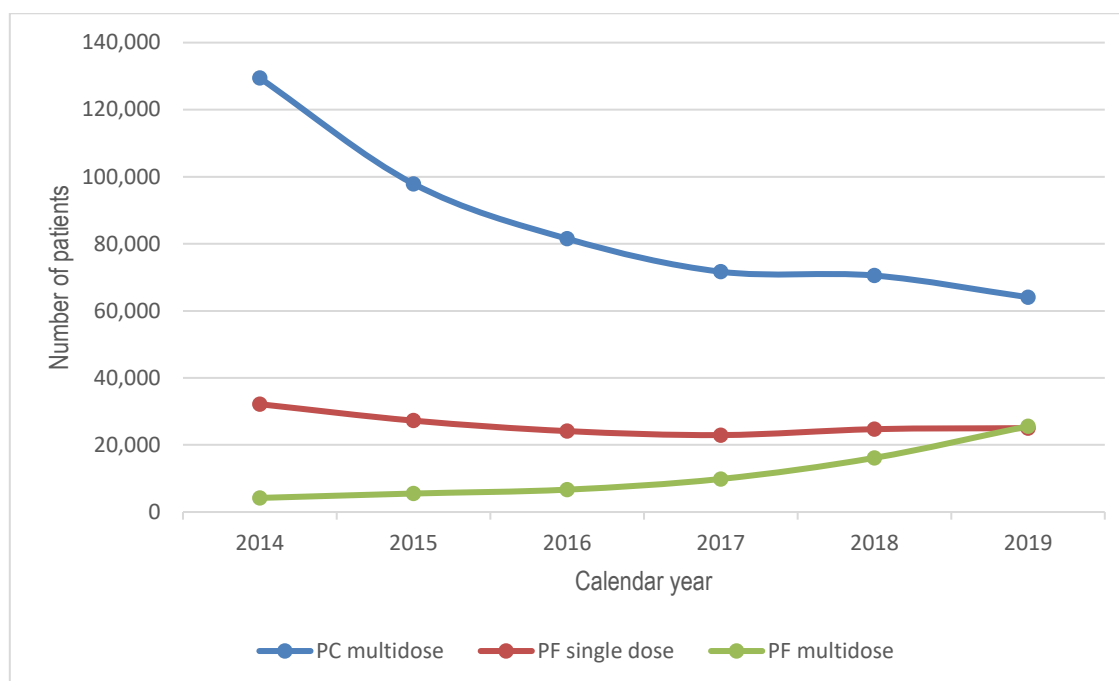


Figure 17: Number of unique patients started on an ocular lubricant for the first time (direct initiation) by calendar year 2014 to 2019

Table 12: Number of unique patients started on an ocular lubricant for the first time (direct initiation) by formulation type and calendar year

Class	2014	2015	2016	2017	2018	2019
PC multidose	129,433 (78.1%)	97,897 (74.9%)	81,519 (72.6%)	71,672 (68.6%)	70,532 (63.3%)	64,066 (55.9%)
PF single dose	32,153 (19.4%)	27,254 (20.9%)	24,132 (21.5%)	22,951 (22%)	24,705 (22.2%)	25,015 (21.8%)
PF multidose	4,203 (2.5%)	5,512 (4.2%)	6,668 (5.9%)	9,853 (9.4%)	16,147 (14.5%)	25,579 (22.3%)
Total	165,789 (100%)	130,663 (100%)	112,319 (100%)	104,476 (100%)	111,384 (100%)	114,660 (100%)

Most patients who were initiated on a PF ocular lubricant were started directly on it without first using a PC ocular lubricant. This is despite the PBS authority listing requirement that a patient be sensitive to preservatives in multi-dose eye drops to be eligible. In 2019 of the 64,661 patients who started a PF ocular lubricant for the first time, 50,594 (78.2%) were directly initiated on a PF ocular lubricant without a prior prescription for a PC ocular lubricant (Figure 18).

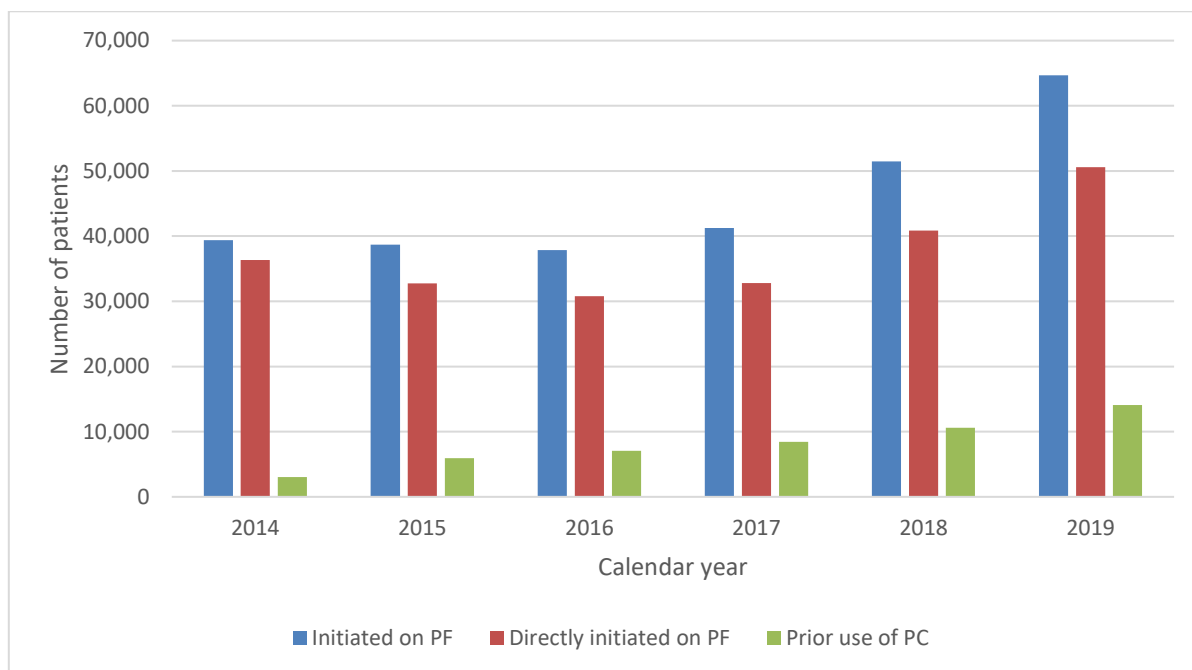


Figure 18: Number of unique patients started on a preservative free (PF) ocular lubricant for the first time – overall (Initiated on PF), without prior use of a PC ocular lubricant (Directly initiated on PF) and with prior use of a PC ocular lubricant (Prior use of PC) - by calendar year 2014 to 2019

There were no obvious changes in the demographics of patients initiated on (or directly initiated on) a PF ocular lubricant over time (Appendix Table B11). In each year approximately 40% of all patients initiated on a PF ocular lubricant were women aged 65+ years. Men aged 65+ years accounted for another 25% of patients starting on a PF ocular lubricant in each year.

A larger proportion of patients who had previously used a PC ocular lubricant were 65+ years age group at the time they were initiated on a PF ocular lubricant than among patients directly initiated onto a PF ocular lubricant (Table 13). However, this would be expected among patients who have trialled another medicine prior to starting a PF ocular lubricant.

Table 13: Age and gender distribution of patients started on a PF ocular lubricant in 2019 for the first time by prior PC use

Characteristic	Male 0–14 years	Male 15–44 years	Male 45–64 years	Male 65+ years	Female 0–14 years	Female 15–44 years	Female 45–64 years	Female 65+ years
Prior PC use (N=14,067)	0.1%	0.9%	5.4%	28.9%	0.1%	2.1%	13.9%	48.6%
No prior PC use (Directly initiated on PF ocular lubricant; N=50,594)	0.6%	3.7%	7.9%	24.9%	0.5%	5.7%	16.3%	40.4%

Duration of therapy

The median number of prescriptions (including the initial prescription) dispensed to patients in the two years after they were directly initiated on an ocular lubricant, regardless of whether it was preservative free or preservative containing, was 2.0 across all years. The mean number of PC prescriptions in the subsequent two years fell slightly over the study period whereas the mean number of PF prescriptions increased (Table 18).

Table 14: Number of ocular lubricant prescriptions that were dispensed to unique patients in the two years after initiation of therapy (including the initial prescription)

	2014	2015	2016	2017
Any ocular lubricant				
Mean	4.76	4.45	4.39	4.45
Mode	1.00	1.00	1.00	1.00
Median	2.00	2.00	2.00	2.00
PC formulation				
Mean	4.66	4.34	4.28	4.22
Mode	1.00	1.00	1.00	1.00
Median	2.00	2.00	2.00	2.00
PF formulation				
Mean	3.88	3.75	3.73	4.01
Mode	1.00	1.00	1.00	1.00
Median	2.00	2.00	2.00	2.00

Switching and co-administration

While the number of patients started on a PC ocular lubricant has been falling year on year, the majority of patients who are started on this type of formulation are not switched to a PF ocular lubricant in subsequent years. Fewer than 10% of patients started on a PC ocular lubricant are switched to a PF ocular lubricant in subsequent years (Table 15).

Once patients have been switched from a PC ocular lubricant to a PF ocular lubricant, few are dispensed another PC ocular lubricant (co-administration). In the two years after a patient had been switched from a PC ocular lubricant to a PF ocular lubricant, 1.9% or fewer patients had been prescribed another PC ocular lubricant (Table 15).

Table 15: Number of unique patients started on a PC ocular lubricant by subsequent therapy

	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)
Including all subsequent calendar years of follow-up				
No subsequent PF use	112,157 (86.7%)	86,846 (88.7%)	73,482 (90.1%)	65,620 (91.6%)
Switched to PF	10,784 (8.3%)	7,449 (7.6%)	5,658 (6.9%)	4,319 (6.0%)
Dispensed another PC ocular lubricant after being switched to a PF ocular lubricant (co-administration)	6,492 (5.0%)	3,602 (3.7%)	2,379 (2.9%)	1,733 (2.4%)
Including only two subsequent years of follow-up (from initiation of PC ocular lubricant				
No subsequent PF use	121,345 (93.8%)	92,053 (94%)	76,467 (93.8%)	66,603 (92.9%)
Switched to PF	5,641 (4.4%)	4,188 (4.3%)	3,706 (4.5%)	3,672 (5.1%)
Dispensed another PC ocular lubricant after being switched to a PF ocular lubricant (co-administration)	2,447 (1.9%)	1,656 (1.7%)	1,346 (1.7%)	1,397 (1.9%)

While most patients started on a PC ocular lubricant are not switched to a PF ocular lubricant, Figure 19 and Table 16 show the average time from the day a patient was started on a PC ocular lubricant to the date of the switch to a PF ocular lubricant (for both patients who remained on the PF ocular lubricant and for patients who later received another PC ocular lubricant [co-administration]). If a switch occurs, it is most likely to occur within the first 100 days of initiation of a PC ocular lubricant.

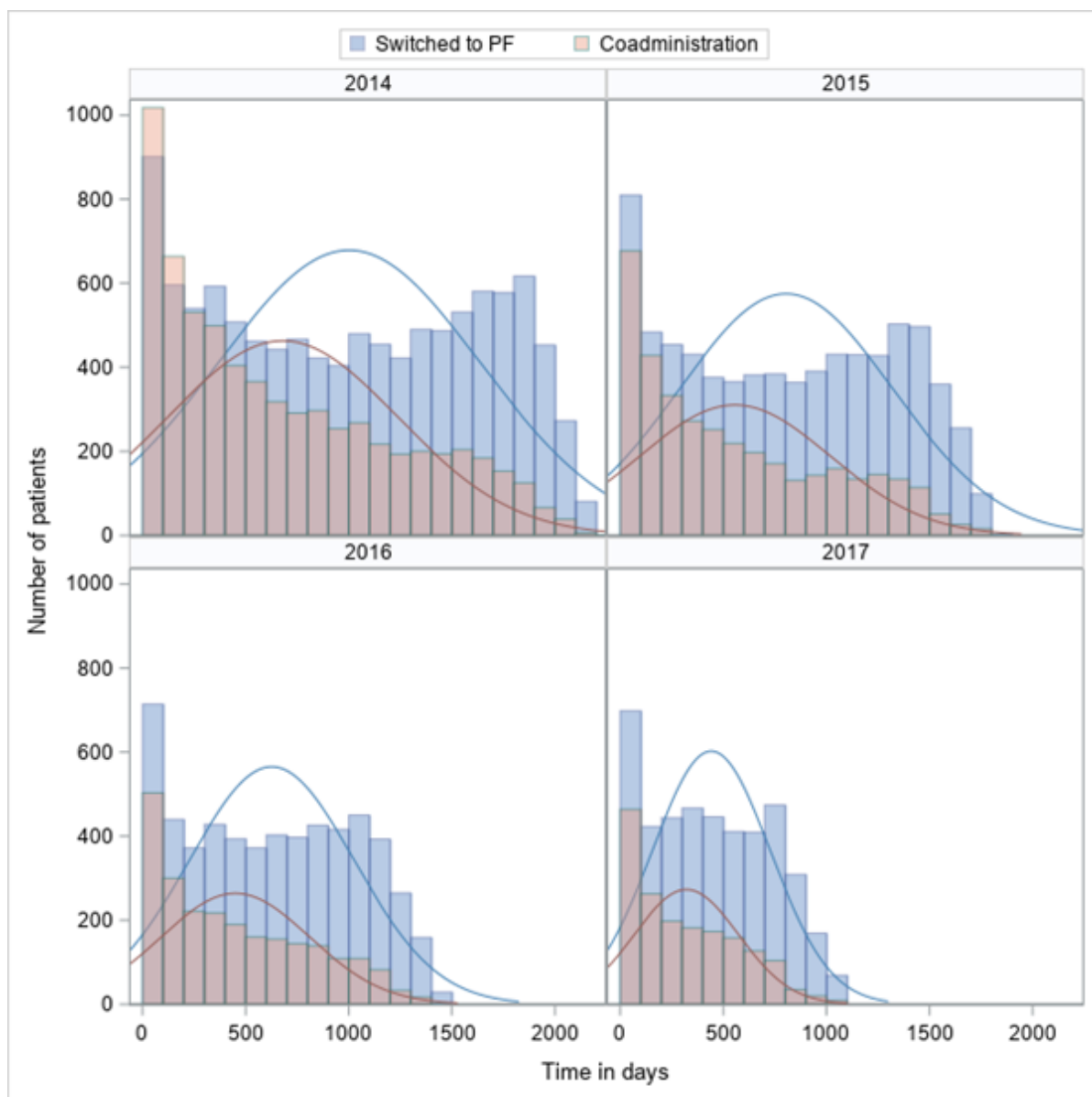


Figure 19: Time (in days) between the date a patient was first dispensed a PC ocular lubricant to being switched to PF ocular lubricant among a) patients switched to a PF ocular lubricant and b) patients who are later dispensed another PC ocular lubricant (co-administration)

When follow-up is restricted to the two years following the date on which they initiated the PC ocular lubricant there has been no change in the mean or median time between starting a PC ocular lubricant and being switched to a PF ocular lubricant.

Table 16: Time (in days) to first use of PF ocular lubricants among patients switched from PC ocular lubricants

	2014	2015	2016	2017
Including all subsequent calendar years of follow-up (from initiation of PC ocular lubricant)				
Mean	1001.9	804.4	626.5	441.7
Mode	56	7	28	14
Median	1011	810	627	427
Including only two subsequent years of follow-up (from initiation of PC ocular lubricant)				
Mean	337.4	327.0	343.4	347.2
Mode	28	7	7	14
Median	330	311	340	350

Discussion

In 2019, there were 1.86 million ocular lubricant prescriptions dispensed on the PBS at a cost of \$31.6 million. This included 1.10 million multidose PC ocular lubricant prescriptions, 445,386 single dose PF prescriptions and 312,139 multidose PF prescriptions.

Since 2013, the number of ocular lubricants dispensed on the PBS has fallen by 7.9% while expenditure has increased by \$9.2 million.

While the number of PC ocular lubricant prescriptions has fallen 32.7%, use of PF ocular lubricants has increased. Since 2013, there has been a 1573% increase in multidose PF ocular lubricant prescription numbers and a 22.0% increase in single dose PF ocular lubricant prescription numbers.

Since 2013, expenditure on all ocular lubricants has increased by 40.9%. This has been driven almost entirely by an \$8.3 million (1622%) increase in expenditure on the multidose PF ocular formulations. In 2019, expenditure on multidose PF sodium hyaluronate alone cost \$7.70 million, accounting for 37.1% of PBS expenditure on all PF ocular lubricants and 24.3% of PBS expenditure on all ocular lubricants. Despite a 32.7% decrease in the number of prescriptions for PC ocular lubricants between 2013 and 2019, overall cost to government for these products has not decreased due to changes in the dispensed price.

While three new multidose PF ocular lubricants were added to the PBS over the study period, this does not explain the large rise in the number of multidose PF prescriptions. Two were only added to the PBS during the last month of the study period (Evolve Carmellose and Evolve Hypromellose) and the third – perfluorohexyloctane (Novatears) – only accounted for 10% of all multidose PF ocular lubricant prescriptions in 2019.

Instead, the increase is almost entirely attributable to increasing use of multidose PF sodium hyaluronate (Hylo-Fresh or Hylo-Forte). In 2019 it was the second most common ocular lubricant prescription on the PBS (271,709 prescriptions). Only one other ocular lubricant, the multidose PC ocular lubricant, polyethylene glycol-400 + propylene glycol

(Systane), was dispensed more commonly in 2019 (359,973 prescriptions). However, over the study period the number of sodium hyaluronate prescriptions dispensed increased by 2197% while the number of polyethylene glycol-400+ propylene glycol prescriptions decreased by 21.3%.

There has been a 508% increase in patients directly started on PF multidose ocular lubricants. Most patients started on a PF ocular lubricant appeared to have been directly initiated on PF ocular lubricants without first using a PC ocular lubricant. This could be because:

- patients have previously trialled over-the-counter or private PC or PF ocular lubricants before being dispensed their first PBS prescriptions (which would not be picked up in PBS data);
- of a clinical preference for PF ocular lubricants given difficulties in clearly classifying symptom severity, limited PBS guidance as to what constitutes severe dry eye syndrome, and international and Australian guidance that states that PF formulations are preferred for patients with severe dry eye syndrome while PC formulations may worsen symptoms.^{6,7,11}

The increase in use and expenditure on PF ocular lubricants seems to be driven by an increase in patients being directly initiated upon PF ocular lubricants rather than switching. While the number of patients started on a PC ocular lubricant has been falling year on year, fewer than 10% of patients who are started on this type of formulation are switched to a PF ocular lubricant in subsequent years.

While the absolute number of patients who were dispensed a PF ocular lubricant has risen and the absolute number of patients prescribed a PC ocular lubricant has fallen, there does not appear to have been any significant shift in the demographics of patients prescribed an ocular lubricant. Consistent with the epidemiology of dry eye syndrome, the majority of patients who were dispensed at least one ocular lubricant were women aged 65+ years.

The bulk of PBS prescriptions for ocular lubricants are prescribed to concessional patients rather than general patients. This is likely a reflection of the prices of ocular lubricants. For non-concession card holders, there would be no real benefit to getting a prescription for an ocular lubricant as the price of each formulation (\$14–37) is under the general patient co-payment and many formulations can be bought over the counter. However, for concession card holders who have a lower co-payment, it would be cheaper to have these medicines dispensed on the PBS.

DUSC consideration

DUSC considered the utilisation reports prepared by NPS MedicineWise using its MedicineInsight data and a 10% PBS sample. DUSC considered that the addition of MedicineInsight data to the reporting gave a useful perspective about patient management through primary care. DUSC noted the MedicineInsight sample did not identify patients in aged care facilities.

DUSC commented that both reports were comprehensive and noted that there was a large ocular lubricant market with a total of 54 listings on the PBS, and of those listings, 12 are preservative-free, multi-dose products.

DUSC noted:

- Its previous consideration of ocular lubricants in June 2014, where the total number of prescriptions had been steady for 10 years (to 2013) and expenditure across the whole group of ocular lubricants had been stable. In 2013, 85% of prescriptions were for multi-dose products, and that the prescription of single dose units had gradually increased from 6.7% in 2003, to 15% in 2013.
- That there is a large variance in the prevalence of dry eyes and there has been substantial growth in the use of PF ocular lubricants, with rising costs driven mainly by increased uptake of hyaluronate sodium.
- The multi-dose PF products were listed on the PBS at a higher price compared to PC products.
- There is a lack of clinical criteria for the diagnosis of severe dry eye disease and guidance for its treatment.
 - There is substantial ongoing growth in the market which may indicate that stricter restriction criteria is required.
- PBS criteria to access PF products is not being adhered to in a large proportion of patients.
 - Most patients who were initiated on a PF ocular lubricant were started directly on it without first using a PC ocular lubricant. This is despite the PBS authority listing requirement that a patient must be sensitive to preservatives in multi-dose eye drops to be eligible. This was observed in the MedicineInsight general practice data which also accounted for the use of over-the-counter products.
- There appears to be low levels of co-administration and switching between products.
 - While the number of patients started on a PC ocular lubricant has decreased year on year, the majority of patients who are started on this type of formulation are not switched to a PF listing in subsequent years. Fewer than 10% of patients started on a PC listing were switched to a PF listing in subsequent years.
 - Once patients have been switched from a PC to a PF ocular lubricant, few are dispensed another PC listing as co-administration. DUSC noted that in the two years after a patient had been switched from a PC to a PF product, 1.9% or fewer patients had been prescribed another PC product.

DUSC actions

DUSC requested that the report be provided to the PBAC for consideration.

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

The sponsors' have no comment.

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.

To the extent provided by law, DoH makes no warranties or representations as to accuracy or completeness of information contained in this report.

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Appendices

Appendix A: Ocular lubricant history from 2012 onwards

Table A1: History of ocular lubricants on the PBS

Date	Drug	Detail
1 December 2012	Hyaluronic acid (Hylo-Forte)	PBS listing: 02171G, 02181T, 02184Y, 02253N
30 September 2013	Carbomer Eye gel 2 mg per g, 10 g NB: Geltears brand only	Delisting: GelTears brand only 08384G, 09210R
30 April 2014	Carbomer with triglyceride lipids: Eye gel 2 mg-10 mg per g, 10 g (Artelac)	Delisting: 02041K, 02044N, 02082N
30 September 2014	Polyethylene glycol 400 (Blink Intensive Tears) <ul style="list-style-type: none"> Eye drops 2.5 mg per mL, 15 mL Eye drops 2.5 mg per mL, single dose units 0.4 mL, 20 Eye drops 2.5 mg per mL, 15 mL Eye drops 2.5 mg per mL, 15 mL Eye drops 2.5 mg per mL, single dose units 0.4 mL, 20 	Delisting: 05559N, 05560P, 09491M, 09492N, 09493P
31 March 2015	Polyvinyl alcohol Eye drops 30 mg per mL, 15 mL (Liquifilm Forte, PVA Forte)	Delisting: 05525T, 02681D, 09222J
30 April 2015	Carbomer with triglyceride lipids: Eye gel 2 mg-10 mg per g, single dose units 0.6 g, 30 (Artelac)	Delisting: 02058H, 02090B
31 March 2016	Carmellose with glycerin (Eye drops containing carmellose sodium 5 mg with glycerin 9 mg per mL, single dose units 0.4 mL, 30 (Optive)	Delisting: 05561Q, 09307W
1 September 2018	Perfluorohexyloctane (Novatears)	PBS listing: 11439C, 11446K
31 October 2018	Carmellose (Theratears) <ul style="list-style-type: none"> Eye drops containing carmellose sodium 2.5 mg per mL, single dose units 0.6 mL, 24 Ocular lubricating gel containing carmellose sodium 10 mg per mL, single dose units 0.6 mL, 28 	Delisting: 05509Y, 05510B, 8823J, 8824K
1 March 2019	Hypromellose (Genteal, In a Wink Moisturising)	PBS listing: 1625W, 11634H, 11634H, 11643T
30 April 2019	Polyvinyl alcohol <ul style="list-style-type: none"> Eye drops 14 mg per mL, 15 mL contains sodium chlorite/hydrogen peroxide as preservative (Vistil) 	Delisting: 05527X, 05528Y, 08831T, 08832W, 09221H, 09223K

Date	Drug	Detail
	<ul style="list-style-type: none"> Eye drops 30 mg per mL, 15 mL contains sodium chlorite/hydrogen peroxide as preservative (Vistil Forte) 	
31 July 2019	Hypromellose Eye drops 3 mg per mL, 15 mL (Genteal, In a Wink Moisturising)	Delisting: 05518K, 08287E, 09213X
1 December 2019	Evolve Hypromellose	PBS listing: 11842G, 11849P
1 December 2019	Evolve Carmellose (Evolve Carmellose)	PBS listing: 11852T ,11853W

Appendix B: Number and cost of prescriptions and demographics of patients by different formulations of ocular lubricants

Table B1: Number and proportion of dispensed prescriptions of preservative free (PF) ocular lubricants by active ingredient and calendar year

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Preservative free single dose							
PF carbomer 974P (5502N & 8514D)	24,466 (6.7%)	25,388 (6.5%)	25,786 (6.3%)	26,038 (6.5%)	26,583 (6.7%)	29,170 (6.9%)	30,601 (6.9%)
PF carbomer 980 (5504Q & 8578L)	6,730 (1.8%)	7,411 (1.9%)	7,627 (1.9%)	7,381 (1.9%)	6,347 (1.6%)	6,467 (1.5%)	7,134 (1.6%)
PF carbomer + triglycerides (2058H & 2090B – delisted Apr 2015)	812 (0.2%)	1,277 (0.3%)	43 (0%)	-	-	-	-
PF carmellose (2324H, 2338C, 5505R, 5506T, 5509Y, 5510B, 8823J & 8824K)	185,464 (50.8%)	192,372 (49%)	195,971 (47.7%)	196,412 (49.3%)	182,799 (46%)	177,940 (41.9%)	178,702 (40.1%)
PF carmellose + glycerol (5561Q & 9307W – delisted Mar 2016)	16,116 (4.4%)	20,449 (5.2%)	26,842 (6.5%)	6,199 (1.6%)	-	-	-
PF dextran-70 + hypromellose (5521N & 8299T)	89,148 (24.4%)	97,054 (24.7%)	102,010 (24.8%)	106,668 (26.8%)	120,027 (30.2%)	141,975 (33.5%)	155,715 (35%)
PF polyethylene glycol (5560P & 9493P – delisted Sept 2014)	3,108 (0.9%)	2,117 (0.5%)	-	-	-	-	-
PF polyethylene glycol + propylene glycol (5532E & 9170P)	39,269 (10.8%)	46,410 (11.8%)	52,298 (12.7%)	55,744 (14%)	61,877 (15.6%)	68,822 (16.2%)	73,234 (16.4%)
Preservative free multidose							
PF carmellose (11852T & 11853W – listed Dec 2019)	-	-	-	-	-	-	12 (0.0%)
PF hypromellose (11842G & 11849P – listed Dec 2019)	-	-	-	-	-	-	<5 (0.0%)
PF hyaluronate sodium (2171G, 2181T, 2184Y & 2253N)	11,831 (63.4%)	27,549 (71%)	49,877 (81.4%)	74,161 (87.2%)	113,419 (91.8%)	178,361 (93.2%)	271,709 (87%)
perfluorohexyloctane (11439C & 11446K – listed Sept 2018)	-	-	-	-	-	3,433 (1.8%)	31,295 (10%)

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
PF soy lecithin + tocopherol + vitamin A (5545W & 9448G)	6,823 (36.6%)	11,271 (29%)	11,397 (18.6%)	10,844 (12.8%)	10,167 (8.2%)	9,615 (5%)	9,121 (2.9%)

Table B2: Number and proportion of dispensed prescriptions of preservative containing (PC) ocular lubricants by active ingredient and calendar year

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Preservative containing multidose							
PC carbomer 980 (5503P, 8384G & 9210R)	102,840 (6.3%)	93,474 (5.7%)	86,239 (5.8%)	75,891 (5.6%)	55,957 (4.5%)	50,803 (4.3%)	48,981 (4.5%)
PC carbomer + triglycerides (2041K, 2044N & 2082N – delisted Apr 2014)	3,287 (0.2%)	990 (0.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
PC carmellose (5507W, 5508X, 8548X, 8593G, 9211T & 9212W)	400,253 (24.5%)	364,559 (22.1%)	331,071 (22.2%)	291,123 (21.4%)	256,813 (20.7%)	238,693 (20%)	219,010 (19.9%)
PC carmellose + glycerol (5556K, 9355J & 9356K)	115,659 (7.1%)	120,198 (7.3%)	119,841 (8%)	115,722 (8.5%)	110,548 (8.9%)	109,173 (9.2%)	101,178 (9.2%)
PC dextran-70 + hypromellose (1509K, 5520M & 9216C)	164,868 (10.1%)	269,776 (16.4%)	218,495 (14.7%)	207,305 (15.2%)	187,927 (15.1%)	174,022 (14.6%)	156,370 (14.2%)
PC hypromellose (2956N, 5517J, 5518K, 8287E, 9213X, 9214Y, 11625W, 11634H & 11643T)	170,034 (10.4%)	154,386 (9.4%)	141,814 (9.5%)	123,664 (9.1%)	109,989 (8.9%)	102,118 (8.6%)	86,069 (7.8%)
PC hypromellose + carbomer 980 (5519L, 8564R & 9215B)	130,705 (8%)	127,511 (7.7%)	117,617 (7.9%)	105,875 (7.8%)	101,079 (8.1%)	100,268 (8.4%)	95,810 (8.7%)
PC polyethylene glycol (5559N, 9491M & 9492N – delisted Sept 2014)	14,674 (0.9%)	8,971 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
PC polyethylene glycol + propylene glycol (5524R, 8676P & 9219F)	457,548 (28%)	439,872 (26.7%)	420,693 (28.2%)	393,169 (28.9%)	376,586 (30.4%)	377,273 (31.7%)	359,973 (32.7%)
PC polyvinyl alcohol (2681D, 2682E,	74,075 (4.5%)	66,920 (4.1%)	54,431 (3.7%)	47,100 (3.5%)	41,547 (3.3%)	38,624 (3.2%)	32,445 (2.9%)

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
5525T, 5526W, 5527X, 5528Y, 8831T, 8832W, 9221H, 9222J, 9223K & 9220G)							

Table B3: Cost to government (\$) of dispensed prescriptions of preservative free (PF) ocular lubricants by active ingredient and calendar year

Class	2013 No.	2014 No.	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.
Preservative free single dose							
PF carbomer 974P (5502N & 8514D)	743,277	783,435	799,086	770,495	791,225	807,653	806,673
PF carbomer 980 (5504Q & 8578L)	202,456	217,578	224,773	217,459	190,996	198,506	217,771
PF carbomer + triglycerides (2058H & 2090B – delisted Apr 2015)	22,500	35,944	1,230	-	-	-	-
PF carmellose (2324H, 2338C, 5505R, 5506T, 5509Y, 5510B, 8823J & 8824K)	5,728,615	5,429,598	5,465,825	5,294,823	4,827,583	4,333,635	4,146,471
PF carmellose + glycerol (5561Q & 9307W – delisted Mar 2016)	492,571	635,689	830,622	177,733	-	-	-
PF dextran-70 + hypromellose (5521N & 8299T)	2,688,238	2,936,722	3,106,253	3,259,926	3,714,642	4,400,417	4,833,094
PF polyethylene glycol (5560P & 9493P – delisted Sept 2014)	102,552	68,052	-	-	-	-	-
PF polyethylene glycol + propylene glycol (5532E & 9170P)	1,176,618	1,395,129	1,580,116	1,624,999	1,806,228	1,920,915	1,925,823
Preservative free multidose							
PF carmellose (11852T & 11853W – listed Dec 2019)	-	-	-	-	-	-	272
PF hypromellose (11842G & 11849P – listed Dec 2019)	-	-	-	-	-	-	<100
PF hyaluronate sodium (2171G, 2181T, 2184Y & 2253N)	304,538	743,833	1,409,824	2,127,655	3,313,199	5,076,077	7,696,050

Class	2013 No.	2014 No.	2015 No.	2016 No.	2017 No.	2018 No.	2019 No.
perfluorohexyloctane (11439C & 11446K – listed Sept 2018)	-	-	-	-	-	91,642	826,479
PF soy lecithin + tocopherol + vitamin A (5545W & 9448G)	206,400	339,336	344,512	319,316	304,166	288,097	276,453

Table B4: Cost to government (\$) of dispensed prescriptions of preservative containing (PC) ocular lubricants by active ingredient and calendar year

Class	2013	2014	2015	2016	2017	2018	2019
Preservative containing multidose							
PC carbomer 980 (5503P, 8384G & 9210R)	677,528	575,779	672,292	691,170	521,620	494,186	480,236
PC carbomer + triglycerides (2041K, 2044N & 2082N – delisted Apr 2014)	19,783	4,213	-	-	-	-	-
PC carmellose (5507W, 5508X, 8548X, 8593G, 9211T & 9212W)	2,738,703	2,531,077	2,870,068	2,823,576	2,559,044	2,384,952	2,157,075
PC carmellose + glycerol (5556K, 9355J & 9356K)	790,971	835,841	1,049,126	1,132,667	1,108,662	1,094,639	999,848
PC dextran- 70 + hypromellose (1509K, 5520M & 9216C)	892,315	1,835,345	1,769,060	2,007,878	1,868,168	1,776,012	1,608,167
PC hypromellose (2956N, 5517J, 5518K, 8287E, 9213X, 9214Y, 11625W,	1,085,118	996,899	1,162,283	1,161,944	1,062,990	1,012,297	818,073

Class	2013	2014	2015	2016	2017	2018	2019
11634H & 11643T)							
PC hypromellose + carbomer 980 (5519L, 8564R & 9215B)	847,946	835,819	977,530	1,004,933	992,431	1,012,719	974,630
PC polyethylene glycol (5559N, 9491M & 9492N – delisted Sept 2014	101,957	54,801	-	-	-	-	-
PC polyethylene glycol + propylene glycol (5524R, 8676P & 9219F)	3,172,954	3,092,707	3,703,070	3,837,200	3,761,810	3,794,973	3,558,038
PC polyvinyl alcohol (2681D, 2682E, 5525T, 5526W, 5527X, 5528Y, 8831T, 8832W, 9221H, 9222J, 9223K & 9220G)	466,168	428,947	434,525	434,996	393,900	377,506	315,567
Any PC multidose formulation	10,793,444	11,191,428	12,637,954	13,094,365	12,268,626	11,947,283	10,911,634

Table B5: Number and proportion of dispensed prescriptions of ocular lubricant by type of formulation and patient status

Prescriber	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Preservative free single dose							
General patient	46,655 (12.8%)	35,750 (9.1%)	34,751 (8.5%)	31,810 (8%)	28,067 (7.1%)	30,044 (7.1%)	28,870 (6.5%)

Prescriber	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Concessional PBS/RPBS patient	309,830 (84.9%)	338,881 (86.3%)	360,442 (87.8%)	353,339 (88.7%)	357,563 (89.9%)	382,569 (90.1%)	404,267 (90.8%)
Under co- payment	8,628 (2.4%)	17,847 (4.5%)	15,384 (3.7%)	13,293 (3.3%)	12,003 (3%)	11,761 (2.8%)	12,249 (2.8%)
Total	365,113 (100%)	392,478 (100%)	410,577 (100%)	398,442 (100%)	397,633 (100%)	424,374 (100%)	445,386 (100%)
Preservative free multidose							
General patient	2,213 (11.9%)	3,815 (9.8%)	5,127 (8.4%)	6,627 (7.8%)	9,610 (7.8%)	14,801 (7.7%)	22,315 (7.1%)
Concessional PBS/RPBS patient	14,434 (77.4%)	31,437 (81%)	51,975 (84.8%)	73,842 (86.9%)	109,128 (88.3%)	169,579 (88.6%)	278,456 (89.2%)
Under co- payment	2,007 (10.8%)	3,568 (9.2%)	4,172 (6.8%)	4,536 (5.3%)	4,848 (3.9%)	7,029 (3.7%)	11,368 (3.6%)
Total	18,654 (100%)	38,820 (100%)	61,274 (100%)	85,005 (100%)	123,586 (100%)	191,409 (100%)	312,139 (100%)
Preservative containing multidose							
General patient	180,628 (11.1%)	173,189 (10.5%)	149,977 (10.1%)	128,546 (9.5%)	111,586 (9.0%)	107,159 (9.0%)	88,794 (8.1%)
Concessional PBS/RPBS patient	1,414,533 (86.6%)	1,438,020 (87.3%)	1,307,955 (87.8%)	1,201,734 (88.4%)	1,101,098 (88.8%)	1,055,555 (88.6%)	982,146 (89.3%)
Under co- payment	38,782 (2.4%)	35,448 (2.2%)	32,269 (2.2%)	29,569 (2.2%)	27,762 (2.2%)	28,260 (2.4%)	28,896 (2.6%)
Total	1,633,943 (100%)	1,646,657 (100%)	1,490,201 (100%)	1,359,849 (100%)	1,240,446 (100%)	1,190,974 (100%)	1,099,836 (100%)

Table B6: Number of patients dispensed prescriptions of preservative free (PF) single dose ocular lubricants by age, sex, age-sex and calendar year

Characteristic	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Total	105,601 (100%)	115,585 (100%)	120,603 (100%)	120,597 (100%)	120,650 (100%)	125,208 (100%)	131,678 (100%)
Sex							
Male	28,597 (27.1%)	31,888 (27.6%)	33,637 (27.9%)	34,156 (28.3%)	34,366 (28.5%)	36,319 (29%)	39,072 (29.7%)

Characteristic	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Female	77,004 (72.9%)	83,697 (72.4%)	86,966 (72.1%)	86,441 (71.7%)	86,284 (71.5%)	88,889 (71%)	92,606 (70.3%)
Age							
0–14 years	472 (0.4%)	471 (0.4%)	495 (0.4%)	555 (0.5%)	572 (0.5%)	648 (0.5%)	634 (0.5%)
15–44 years	4,990 (4.7%)	4,970 (4.3%)	4,927 (4.1%)	4,696 (3.9%)	4,308 (3.6%)	4,610 (3.7%)	4,792 (3.6%)
45–64 years	20,254 (19.2%)	20,887 (18.1%)	20,859 (17.3%)	20,082 (16.7%)	19,794 (16.4%)	20,360 (16.3%)	20,991 (15.9%)
65+ years	79,885 (75.6%)	89,257 (77.2%)	94,322 (78.2%)	95,264 (79%)	95,976 (79.5%)	99,590 (79.5%)	105,261 (79.9%)
Age-sex							
Male 0–14 years	258 (0.2%)	271 (0.2%)	286 (0.2%)	319 (0.3%)	321 (0.3%)	371 (0.3%)	363 (0.3%)
Male 15–44 years	1,738 (1.6%)	1,763 (1.5%)	1,773 (1.5%)	1,708 (1.4%)	1,533 (1.3%)	1,646 (1.3%)	1,798 (1.4%)
Male 45–64 years	4,873 (4.6%)	5,007 (4.3%)	5,174 (4.3%)	5,028 (4.2%)	4,987 (4.1%)	5,273 (4.2%)	5,723 (4.3%)
Male 65+ years	21,728 (20.6%)	24,847 (21.5%)	26,404 (21.9%)	27,101 (22.5%)	27,525 (22.8%)	29,029 (23.2%)	31,188 (23.7%)
Female 0–14 years	214 (0.2%)	200 (0.2%)	209 (0.2%)	236 (0.2%)	251 (0.2%)	277 (0.2%)	271 (0.2%)
Female 15–44 years	3,252 (3.1%)	3,207 (2.8%)	3,154 (2.6%)	2,988 (2.5%)	2,775 (2.3%)	2,964 (2.4%)	2,994 (2.3%)
Female 45–64 years	15,381 (14.6%)	15,880 (13.7%)	15,685 (13%)	15,054 (12.5%)	14,807 (12.3%)	15,087 (12%)	15,268 (11.6%)
Female 65+ years	58,157 (55.1%)	64,410 (55.7%)	67,918 (56.3%)	68,163 (56.5%)	68,451 (56.7%)	70,561 (56.4%)	74,073 (56.3%)

Table B7: Number of patients dispensed prescriptions of preservative free (PF) multidose ocular lubricants by age, sex, age-sex and calendar year

Characteristic	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Total	6,938	12,338	17,791	23,373	33,541	52,134	83,035
Sex							
Male	1,928 (27.8%)	3,513 (28.5%)	5,239 (29.4%)	6,936 (29.7%)	10,171 (30.3%)	15,709 (30.1%)	25,184 (30.3%)
Female	5,010 (72.2%)	8,825 (71.5%)	12,552 (70.6%)	16,437 (70.3%)	23,370 (69.7%)	36,425 (69.9%)	57,851 (69.7%)

Characteristic	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Age							
0–14 years	17 (0.2%)	37 (0.3%)	85 (0.5%)	81 (0.3%)	148 (0.4%)	198 (0.4%)	286 (0.3%)
15–44 years	422 (6.1%)	714 (5.8%)	910 (5.1%)	1,144 (4.9%)	1,539 (4.6%)	2,266 (4.3%)	3,571 (4.3%)
45–64 years	1,566 (22.6%)	2,584 (20.9%)	3,397 (19.1%)	4,295 (18.4%)	5,957 (17.8%)	8,950 (17.2%)	13,976 (16.8%)
65+ years	4,933 (71.1%)	9,003 (73%)	13,399 (75.3%)	17,853 (76.4%)	25,897 (77.2%)	40,720 (78.1%)	65,202 (78.5%)
Total	6,938 (100%)	12,338 (100%)	17,791 (100%)	23,373 (100%)	33,541 (100%)	52,134 (100%)	83,035 (100%)
Age-sex							
Male 0–14 years	9 (0.1%)	22 (0.2%)	48 (0.3%)	43 (0.2%)	94 (0.3%)	104 (0.2%)	154 (0.2%)
Male 15–44 years	151 (2.2%)	228 (1.8%)	313 (1.8%)	401 (1.7%)	528 (1.6%)	714 (1.4%)	1,219 (1.5%)
Male 45–64 years	370 (5.3%)	636 (5.2%)	869 (4.9%)	1,111 (4.8%)	1,548 (4.6%)	2,281 (4.4%)	3,542 (4.3%)
Male 65+ years	1,398 (20.1%)	2,627 (21.3%)	4,009 (22.5%)	5,381 (23%)	8,001 (23.9%)	12,610 (24.2%)	20,269 (24.4%)
Female 0–14 years	8 (0.1%)	15 (0.1%)	37 (0.2%)	38 (0.2%)	54 (0.2%)	94 (0.2%)	132 (0.2%)
Female 15–44 years	271 (3.9%)	486 (3.9%)	597 (3.4%)	743 (3.2%)	1,011 (3%)	1,552 (3%)	2,352 (2.8%)
Female 45–64 years	1,196 (17.2%)	1,948 (15.8%)	2,528 (14.2%)	3,184 (13.6%)	4,409 (13.1%)	6,669 (12.8%)	10,434 (12.6%)
Female 65+ years	3,535 (51%)	6,376 (51.7%)	9,390 (52.8%)	12,472 (53.4%)	17,896 (53.4%)	28,110 (53.9%)	44,933 (54.1%)
Total	6,938 (100%)	12,338 (100%)	17,791 (100%)	23,373 (100%)	33,541 (100%)	52,134 (100%)	83,035 (100%)

Table B8: Number of patients dispensed prescriptions of preservative containing (PC) multidose ocular lubricants by age, sex, age-sex and calendar year

Characteristic	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Sex							
Male	127,697 (33.1%)	127,109 (33.6%)	117,164 (33.9%)	108,099 (34.4%)	100,566 (34.8%)	98,090 (35.3%)	92,943 (35.5%)

Characteristic	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Female	258,207 (66.9%)	250,985 (66.4%)	228,420 (66.1%)	206,297 (65.6%)	188,590 (65.2%)	179,607 (64.7%)	168,732 (64.5%)
Total	385,904 (100%)	378,094 (100%)	345,584 (100%)	314,396 (100%)	289,156 (100%)	277,697 (100%)	261,675 (100%)
Age							
0–14 years	1,484 (0.4%)	1,605 (0.4%)	1,496 (0.4%)	1,363 (0.4%)	1,251 (0.4%)	1,287 (0.5%)	1,160 (0.4%)
15–44 years	10,847 (2.8%)	11,000 (2.9%)	9,741 (2.8%)	8,602 (2.7%)	7,829 (2.7%)	8,003 (2.9%)	7,420 (2.8%)
45–64 years	49,484 (12.8%)	47,725 (12.6%)	42,192 (12.2%)	37,275 (11.9%)	34,184 (11.8%)	33,778 (12.2%)	31,298 (12%)
65+ years	324,089 (84%)	317,764 (84%)	292,155 (84.5%)	267,156 (85%)	245,892 (85%)	234,629 (84.5%)	221,797 (84.8%)
Total	385,904 (100%)	378,094 (100%)	345,584 (100%)	314,396 (100%)	289,156 (100%)	277,697 (100%)	261,675 (100%)
Age-sex							
Male 0–14 years	833 (0.2%)	918 (0.2%)	853 (0.2%)	761 (0.2%)	668 (0.2%)	745 (0.3%)	633 (0.2%)
Male 15–44 years	3,961 (1%)	4,122 (1.1%)	3,553 (1%)	3,313 (1.1%)	3,022 (1.0%)	3,156 (1.1%)	2,814 (1.1%)
Male 45–64 years	15,891 (4.1%)	15,713 (4.2%)	13,853 (4.0%)	12,330 (3.9%)	11,476 (4.0%)	11,533 (4.2%)	10,843 (4.1%)
Male 65+ years	107,012 (27.7%)	106,356 (28.1%)	98,905 (28.6%)	91,695 (29.2%)	85,400 (29.5%)	82,656 (29.8%)	78,653 (30.1%)
Female 0–14 years	651 (0.2%)	687 (0.2%)	643 (0.2%)	602 (0.2%)	583 (0.2%)	542 (0.2%)	527 (0.2%)
Female 15–44 years	6,886 (1.8%)	6,878 (1.8%)	6,188 (1.8%)	5,289 (1.7%)	4,807 (1.7%)	4,847 (1.7%)	4,606 (1.8%)
Female 45–64 years	33,593 (8.7%)	32,012 (8.5%)	28,339 (8.2%)	24,945 (7.9%)	22,708 (7.9%)	22,245 (8%)	20,455 (7.8%)
Female 65+ years	217,077 (56.3%)	211,408 (55.9%)	193,250 (55.9%)	175,461 (55.8%)	160,492 (55.5%)	151,973 (54.7%)	143,144 (54.7%)
Total	385,904 (100%)	378,094 (100%)	345,584 (100%)	314,396 (100%)	289,156 (100%)	277,697 (100%)	261,675 (100%)

Table B9: Number of patients dispensed prescriptions of preservative free ocular lubricants by active ingredient and calendar year

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Preservative free single dose							
PF carbomer 974P (5502N & 8514D)	7,134	7,444	7,607	7,703	8,064	8,760	9,417
PF carbomer 980 (5504Q & 8578L)	2,198	2,539	2,581	2,534	2,416	2,327	2,503
PF carbomer + triglycerides (2058H & 2090B – delisted Apr 2015)	386	571	32	-	-	-	-
PF carmellose (2324H, 2338C, 5505R, 5506T, 5509Y, 5510B, 8823J & 8824K)	52,437	55,944	57,445	59,845	57,461	54,104	54,283
PF carmellose + glycerol (5561Q & 9307W – delisted Mar 2016)	5,478	6,903	8,709	4,057	-	-	-
PF dextran-70 + hypromellose (5521N & 8299T)	23,643	25,904	27,143	28,113	32,504	37,867	41,727
PF polyethylene glycol (5560P & 9493P – delisted Sept 2014)	1,111	937	-	-	-	-	-
PF polyethylene glycol + propylene glycol (5532E & 9170P)	13,221	15,356	17,093	18,354	20,225	22,158	23,750
Preservative free multidose							
PF carmellose (11852T & 11853W – listed Dec 2019)	-	-	-	-	-	-	10
PF hypromellose (11842G & 11849P – listed Dec 2019)	-	-	-	-	-	-	<5
PF hyaluronate sodium (2171G, 2181T, 2184Y & 2253N)	4,138	8,168	13,790	19,561	29,868	46,931	70,557
perfluorohexyloctane (11439C & 11446K – listed Sept 2018)	-	-	-	-	-	1,803	9,302
PF soy lecithin + tocopherol + vitamin A (5545W & 9448G)	2,801	4,172	4,001	3,812	3,681	3,409	3,166

Table B10: Number of patients dispensed prescriptions of preservative containing ocular lubricants by active ingredient and calendar year

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Preservative containing multidose							
PC carbomer 980 (5503P, 8384G & 9210R)	20,340	18,943	17,687	15,758	13,192	11,589	11,251
PC carbomer + triglycerides (2041K, 2044N & 2082N – delisted Apr 2014)	1,052	480	-	-	-	-	-

Class	2013 No. (%)	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
PC carmellose (5507W, 5508X, 8548X, 8593G, 9211T & 9212W)	81,673	74,894	67,249	59,071	51,980	48,346	44,517
PC carmellose + glycerol (5556K, 9355J & 9356K)	35,845	36,662	36,181	34,438	31,834	30,758	28,076
PC dextran-70 + hypromellose (1509K, 5520M & 9216C)	48,592	59,115	52,503	48,838	44,782	42,180	39,563
PC hypromellose (2956N, 5517J, 5518K, 8287E, 9213X, 9214Y, 11625W, 11634H & 11643T)	39,909	36,321	32,883	28,586	25,762	24,040	21,230
PC hypromellose + carbomer 980 (5519L, 8564R & 9215B)	32,112	31,910	29,901	27,273	26,576	26,120	25,395
PC polyethylene glycol (5559N, 9491M & 9492N – delisted Sept 2014)	4,222	3,121	-	-	-	-	-
PC polyethylene glycol + propylene glycol (5524R, 8676P & 9219F)	105,961	101,911	96,676	90,133	85,964	86,258	84,233
PC polyvinyl alcohol (2681D, 2682E, 5525T, 5526W, 5527X, 5528Y, 8831T, 8832W, 9221H, 9222J, 9223K & 9220G)	16,260	14,788	12,522	10,323	9,133	8,449	7,425

Table B11: Age and sex- profile of patients initiated on preservative free (PF) ocular lubricants by calendar year

Characteristic	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Patients initiated on PF ocular lubricants						
Male 0–14 years	196 (0.5%)	238 (0.6%)	240 (0.6%)	278 (0.7%)	315 (0.6%)	335 (0.5%)
Male 15–44 years	1,209 (3.1%)	1,328 (3.4%)	1,335 (3.5%)	1,291 (3.1%)	1,507 (2.9%)	2,015 (3.1%)
Male 45–64 years	2,747 (7%)	2,973 (7.7%)	2,910 (7.7%)	3,111 (7.5%)	3,695 (7.2%)	4,751 (7.3%)
Male 65+ years	8,969 (22.8%)	9,106 (23.5%)	9,164 (24.2%)	10,394 (25.2%)	12,851 (25%)	16,640 (25.7%)
Female 0–14 years	144 (0.4%)	169 (0.4%)	197 (0.5%)	211 (0.5%)	259 (0.5%)	269 (0.4%)

Characteristic	2014 No. (%)	2015 No. (%)	2016 No. (%)	2017 No. (%)	2018 No. (%)	2019 No. (%)
Female 15–44 years	2,183 (5.5%)	2,159 (5.6%)	2,150 (5.7%)	2,206 (5.4%)	2,676 (5.2%)	3,180 (4.9%)
Female 45–64 years	7,117 (18.1%)	6,699 (17.3%)	6,535 (17.3%)	6,946 (16.8%)	8,577 (16.7%)	10,214 (15.8%)
Female 65+ years	16,830 (42.7%)	16,017 (41.4%)	15,335 (40.5%)	16,796 (40.7%)	21,564 (41.9%)	27,257 (42.2%)
Total	39,395 (100%)	38,689 (100%)	37,866 (100%)	41,233 (100%)	51,444 (100%)	64,661 (100%)
Patients directly initiated on PF ocular lubricants without previously trialling PC ocular lubricants						
Male 0–14 years	190 (0.5%)	223 (0.7%)	225 (0.7%)	264 (0.8%)	303 (0.7%)	320 (0.6%)
Male 15–44 years	1,168 (3.2%)	1,256 (3.8%)	1,252 (4.1%)	1,209 (3.7%)	1,414 (3.5%)	1,890 (3.7%)
Male 45–64 years	2,582 (7.1%)	2,661 (8.1%)	2,564 (8.3%)	2,640 (8%)	3,149 (7.7%)	3,988 (7.9%)
Male 65+ years	8,186 (22.5%)	7,507 (22.9%)	7,239 (23.5%)	7,966 (24.3%)	9,909 (24.3%)	12,576 (24.9%)
Female 0–14 years	141 (0.4%)	163 (0.5%)	188 (0.6%)	205 (0.6%)	244 (0.6%)	257 (0.5%)
Female 15–44 years	2,108 (5.8%)	2,009 (6.1%)	1,992 (6.5%)	2,014 (6.1%)	2,470 (6%)	2,891 (5.7%)
Female 45–64 years	6,677 (18.4%)	5,912 (18%)	5,566 (18.1%)	5,727 (17.5%)	7,015 (17.2%)	8,253 (16.3%)
Female 65+ years	15,304 (42.1%)	13,035 (39.8%)	11,774 (38.2%)	12,779 (39%)	16,348 (40%)	20,419 (40.4%)
Total	36,356 (100%)	32,766 (100%)	30,800 (100%)	32,804 (100%)	40,852 (100%)	50,594 (100%)