

11.4 OCULAR LUBRICANTS

1 Purpose of item

- 1.1 To consider the findings of the DUSC utilisation analysis of ocular lubricants and consider if the current pricing of ocular lubricants is appropriate.

2 Background

- 2.1 At its June 2014 meeting the DUSC considered a utilisation analysis of ocular lubricants.

- 2.2 The DUSC noted that:

- Expenditure across the ocular lubricants has been gradually increasing whilst prescription numbers are fairly stable.
- There is currently a large number of ocular lubricant products listed on the PBS with a variety of prices.
- Currently prices vary both between ocular lubricants that contain a preservative and the ocular lubricants that are preservative free.
- A substantial price differential exists between preservative containing products and preservative free products.

- 2.3 The DUSC referred these matters to the PBAC to consider if the current pricing is appropriate.

- 2.4 Key findings of the analysis included:

- The total number of prescriptions for ocular lubricants has been fairly steady over the last ten years from 2003, 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 over the last ten years has been gradually rising from a low of \$19.7 million in 2006. Expenditure in 2012 was \$26.2 million.
- Almost all prescriptions for ocular lubricants are 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 is gradually increasing. Single dose unit products comprised 1.3% of prescriptions supplied in 1994, 6.7% in 2003, 14% in

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2012 and 15% in 2013 (to end September). This is likely to explain the gradual increase in expenditure on ocular lubricants despite stable prescription numbers.

- The most common prescribers of ocular lubricants are 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.

- 2.5 Ocular lubricant products have been considered by the PBAC as minor submissions and recommended on a cost minimisation basis.
- 2.6 At its June 1992 meeting, the PBAC recommended the listing of carmellose sodium (Celluvisc[®]) single dose unit eye drops as an authority required benefit for severe dry eye syndrome where less costly alternative preparations are inappropriate. In August 1994, the PBAC recommended the listing of carmellose sodium (Cellufresh[®]) single dose unit eye drops with this same restriction on a cost minimisation basis with Celluvisc brand.
- 2.7 In July 2004, the PBAC considered the pricing of multi-dose lubricant eye drops and recommended to the Minister and the PBPA that despite different formulations, all multi-dose lubricant eye drops are considered equivalent for pricing purposes, and any claim for a price advantage would need to be supported by data demonstrating the claimed therapeutic advantage(s) which adequately justify the price advantage.
- 2.8 Over time the prices of multi-dose preparations have become varied, despite being listed on a cost minimisation basis. This is also the case for single dose unit preparations. Preservative free multi dose preparations have also been listed in addition to single dose unit preparations, which are preservative free. Part of the discrepancy in prices has arisen due to the restructure of PBS pricing implemented as part of the 2007 PBS reforms. Application of the 2007 PBS reform pricing policy resulted in a number of ocular lubricants being assigned to the F1 formulary. Additionally, some new brands of ocular lubricants have been listed at lower prices.
- 2.9 Summary tables by preservative containing and preservative free are presented below. Active ingredient, multi-dose or single dose, quantity and prices are also included.

Preservative containing

Drug	Multi-dose or single dose presentation	Preservative	Quantity	Price (DPMQ)*
Carbomer	Multi-dose (gel)	Yes	1 x 10 g	\$10.00
Carmellose	Multi-dose	Yes	1 x 15 mL	\$10.93
Carmellose with glycerine	Multi-dose	Yes	1 x 15 mL	\$10.93
Hypromellose	Multi-dose	Yes	1 x 15 mL	\$10.61
Hypromellose with carbomer 980	Multi-dose (gel)	Yes	1 x 10 g	\$10.61
Hypromellose with dextran	Multi-dose	Yes	1 x 15 mL	\$10.83

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Polyethylene glycol 400 with propylene glycol	Multi-dose	Yes	1 x 15 mL	\$10.93
Polyvinyl alcohol	Multi-dose	Yes	1 x 15 mL	\$10.61

*Brand price premiums excluded.

Preservative free

Drug	Multi-dose or single dose presentation	Preservative	Quantity	Price (DPMQ)*
Carbomer	Single dose units	No	3 x 30	\$36.43
Carbomer 974	Single dose units	No	3 x 30	\$36.40
Carbomer with triglycerides	Single dose units	No	3 x 30	\$36.43
Carmellose (Celluvisc, Cellufresh, Optifresh)	Single dose units	No	3 x 30	\$31.63
Carmellose (TheraTears)	Single dose units	No	4 x 24	\$40.76
			3 x 28	\$34.42
Hyaluronic acid	Multi-dose	No	1 x 10 mL	\$33.96
Hypromellose with dextran	Single dose units	No	3 x 28	\$35.41
Paraffin	Multi-dose (ointment)	No	2 x 5 g	\$21.58
		No	2 x 3.5 g	\$21.58
		No	2 x 3.5 g	\$20.94
Polyethylene glycol 400 with propylene glycol	Single dose units	No	2 x 28	\$34.42
Soy lecithin	Multi-dose (eye spray)	No	2 x 10 mL	\$36.40

*Brand price premiums excluded.

2.10 Therapeutic relativities are used for the purpose of determining a price (for F1 drugs) in accordance with cost-effectiveness requirements. As at 1 August 2014, the current therapeutic relativities exist:

- Hypromellose with dextran single unit eye drop was recommended on a cost minimisation basis compared to carmellose sodium 0.5% single unit eye drop.
- Carbomer 974 lubricating eye gel 0.3% (Poly Gel®) single dose units were listed on a cost minimisation basis compared with carmellose sodium 0.5% eye drop single dose units (Cellufresh®).
- Carbomer 980 ocular gel in single dose units (Viscotears®) was listed on the basis of cost minimisation compared to other listed single dose unit lubricating eye drops.
- Following a review by the PBAC in 2004, the Committee advised that all multi-dose lubricant eye drops should be considered equivalent for pricing purposes, and any claims for a premium would need to be supported by data demonstrating any claimed therapeutic advantages.
- Tamarindus indica seed polysaccharide (TSP) was recommended on a cost minimisation basis compared with carmellose, available as sodium eye drops

(Cellufresh®) 5 mg per ml, single dose units. The equi-effective doses were 2 units of TSP eye drops daily (24 hours) and 3 units of Cellufresh® daily (24 hours).

- Carmellose sodium with glycerin single dose units (Optive®) was recommended on a cost-minimisation basis at the same cost per unit as other carmellose sodium single dose unit products.
- Carbomer with triglyceride lipids multi-dose and single-dose units (Artelac®) were recommended for listing on a cost-minimisation basis with the other PBS listed multi-dose and single dose lubricant eye drops.
- Paraffin with retinyl palmitate eye ointment (VitA-POS®) was recommended for listing on a cost minimisation basis against paraffin eye ointment on a gram for gram basis with no price advantage for the Vitamin A content.
- Sodium hyaluronate was recommended for listing for treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi dose eye drops on the basis of cost minimisation compared to other PBS listed eye products.

3 PBAC Outcome

- 3.1 The PBAC recommended that all ocular lubricants should be considered equivalent for pricing purposes. The PBAC noted that this recommendation includes ocular lubricants that contain a preservative, those that are preservative free, multi-dose products and single dose unit products.
- 3.2 The PBAC considered that no evidence was presented to conclude any difference in patient outcomes between the various ocular lubricants.
- 3.3 The PBAC noted that any submission to the PBAC requesting a price advantage should provide evidence to support any claimed superior patient outcome.
- 3.4 Advice to the Minister under subsection 101(3BA) of the *National Health Act 1953*:
In accordance with subsection 101(3BA) of the *National Health Act 1953*, the PBAC advised that it is of the opinion that carbomer, carbomer 974, carbomer with triglyceride lipids, carmellose, carmellose with glycerin, hyaluronic acid, hypromellose, hypromellose with carbomer 980, hypromellose with dextran, paraffin, polyethylene glycol 400 with propylene glycol, polyvinyl alcohol and soy lecithin should be treated as interchangeable on an individual patient basis.

4 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to

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recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.