

5.19 POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL, Eye drops 4 mg-3 mg per mL, 15 mL, Optix Lubricating Eye Drops®, Petrus Pharmaceuticals Pty Ltd

1 Purpose of Submission

- 1.1 The Committee Secretariat submission sought to list polyethylene glycol 400 0.4% with propylene glycol 0.3%, 15 mL eye drops (Optix®) under the same circumstances as the PBS-listed polyethylene glycol 400 0.4% with propylene glycol 0.3%, 15 mL eye drops (Systane®).
- 1.2 The submission requested that Optix be listed as a new generic medicine to Systane.

2 Background

- 2.1 Systane is listed on the PBS as a Restricted Benefit for severe dry eye syndrome, including Sjogren's syndrome. Systane is currently the only brand of polyethylene glycol 400 0.4% with propylene glycol 0.3%, 15 mL eye drops listed on the PBS for this indication.
- 2.2 Systane is listed as a 15 mL single pack and as a 28 x 0.8 mL unit dose pack. At its November 2021 meeting, the PBAC recommended the listing of a 30 x 0.8 mL unit dose pack, noting that the sponsor intended to delist the 28 x 0.8 mL unit dose pack.
- 2.3 The recommended dosage of Optix is 1-2 drops into each eye 3-4 times a day or as required and is suitable for use with contact lenses.

Registration status

- 2.4 Optix was TGA registered on 26 July 2021 as a Class IIA medical device.
- 2.5 The TGA has approved Optix 'to be used to moisturize, soothe, lubricate and rehydrate dry and tired eyes. To provide temporary relief from discomfort, burning and irritation due to dry eye or prolonged exposure to screens, dust, smoke & sunlight. May also provide overnight hydration in the form of a gel.'

Previous PBAC consideration

- 2.6 Optix has not previously been considered by the PBAC for severe dry eye syndrome, including Sjogren's syndrome.

For more detail on PBAC's view, see section 6 PBAC outcome.

3 Requested listing

3.1 The submission requested the following new listing:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL polyethylene glycol 400 0.4% with propylene glycol 0.3% eye drops, 15 mL	5524R	1	1	5	Systane ^a Optix ^a
POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL polyethylene glycol 400 0.4% with propylene glycol 0.3% eye drops, 15 mL	8676P	1	1	5	Systane ^a Optix ^a
POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL polyethylene glycol 400 0.4% with propylene glycol 0.3% eye drops, 15 mL	9219F	1	1	11	Systane ^a Optix ^a
Restriction Summary 6120 / Treatment of Concept: 6120					
Restriction Summary 6073 / Treatment of Concept: 6073					
Restriction Summary 6098 / Treatment of Concept: 6098					

3.2 The submission requested identical listings to that of the Systane 15 mL single pack for the same indications. The PBAC noted that Systane is currently PBS-listed as a Restricted Benefit for ‘Severe dry eye syndrome, including Sjogren’s syndrome’, and that the Australian Register of Therapeutic Goods (ARTG) Certificate for Optix does not include ‘severe dry eye syndrome’ in its intended purpose.

For more detail on PBAC’s view, see section 6 PBAC outcome.

4 Comparator

4.1 The submission nominated the Systane 15 mL pack as the main comparator. This was appropriate.

For more detail on PBAC’s view, see section 6 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

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

Clinical claim

5.3 The submission claimed non-inferior comparative effectiveness and safety to Systane. The submission did not provide any clinical evidence in support of the clinical claim. The submission highlighted that artificial tears do not require bioequivalence studies and as such, the TGA would not provide an equivalence statement for this product. The PBAC noted that this product required PBAC consideration due to the absence of a TGA equivalence statement, and that it would have otherwise listed as a generic of Systane.

5.4 The submission stated that Optix is pharmaceutically equivalent to Systane as both products contain polyethylene glycol 400 0.4% and propylene glycol 0.3%.

5.5 The PBAC considered that the claim of non-inferior comparative effectiveness and safety was reasonable.

Estimated PBS utilisation and financial implications

5.6 The submission proposed an AEMP of \$[REDACTED], which is lower than the AEMP of Systane (\$2.75 as at June 2022).

5.7 Based on the proposed AEMP, the calculated DPMQ for Optix is: \$[REDACTED]. This is lower than the current DPMQ of Systane (\$15.24 as at June 2022).

5.8 Table 1 presents the estimated extent of use, cost of Optix to the PBS/RPBS and the net financial implications to the PBS/RPBS.

5.9 The submission claimed that the cost of Optix to the PBS/RPBS is expected to be \$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6).

5.10 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of Optix is -\$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to -\$0 to < \$10 million in Year 6).

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	1	2	2	3	3	3
Estimated financial implications of Optix						
Cost to PBS/RPBS less co-payment	4	\$4	\$4	\$4	\$4	\$4
Net financial implications						
Net cost to PBS/RPBS	4	-\$4	-\$4	-\$4	-\$4	-\$4

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Optix Utilisation Cost Model Workbook.

The redacted values correspond to the following ranges:

¹<500

²10,000 to < 20,000

³20,000 to < 30,000

⁴\$0 to < \$10 million

5.11 As this was a Committee Secretariat submission the financial estimates analysis were not independently evaluated.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

6.1 The PBAC recommended the listing of a new generic brand of polyethylene glycol 400 with propylene glycol eye drops (Optix) under the same circumstances as the PBS-listed Systane eye drops, for the treatment of severe dry eye syndrome, including Sjogren's syndrome.

6.2 The PBAC noted that artificial tears do not require bioequivalence studies and as such, a bioequivalence statement from the TGA was not available for this product. The PBAC noted that Systane is currently PBS-listed as a Restricted Benefit for 'Severe dry eye syndrome, including Sjogren's syndrome', and that 'severe dry eye syndrome' was not specifically mentioned in the Optix ARTG Certificate. However, the PBAC noted that both Optix and Systane contain the same active ingredients and therefore accepted that Systane is an appropriate comparator.

6.3 The PBAC noted that the submission requested an AEMP for Optix that was lower than its comparator, Systane. The PBAC noted that the submission estimated Optix will provide a net cost saving of >\$█ to the PBS/RPBS over 6 years.

6.4 The PBAC considered the equi-effective doses to be one drop of Optix and one drop of Systane.

6.5 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Optix eye drops and Systane eye drops, should be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution (i.e. 'a' flagged).

- 6.6 The PBAC advised that, because Optix is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed Systane, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
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POLYETHYLENE GLYCOL 400 + PROPYLENE GLYCOL polyethylene glycol 400 0.4% + propylene glycol 0.3% eye drops, 15 mL	8676P	1	1	5	Systane ^a Optix ^a
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Restriction Summary 6120 / Treatment of Concept: 6120					
Restriction Summary 6073 / Treatment of Concept: 6073					
Restriction Summary 6098 / Treatment of Concept: 6098					

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the

listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.