SMC2720

netarsudil plus latanoprost eye drops solution (Roclanda®)

Santen UK Limited

10 January 2025

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a full submission

netarsudil plus latanoprost (Roclanda®) is accepted for restricted use within NHSScotland.

Indication under review: for the reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction.

SMC restriction: for use in patients for whom treatment with a prostaglandin analogue alone provides insufficient IOP reduction, only if:

- the patient has then tried a fixed-dose combination treatment and it has not sufficiently reduced IOP, or
- a fixed-dose combination treatment containing beta-blockers is unsuitable

In a phase III study, netarsudil plus latanoprost was non-inferior to a prostaglandin analogue plus beta-blocker in mean IOP at week 2, week 6 and month 3.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Netarsudil and latanoprost reduce intraocular pressure by increasing the outflow of aqueous humour via different mechanisms of action. Netarsudil is a Rho kinase inhibitor, which increases trabecular outflow and reduces episcleral venous pressure. Latanoprost is a prostaglandin analogue that increases uveoscleral outflow, and in addition may also reduce IOP by decreasing outflow resistance. The medicine under review is the first fixed-dose combination eye drop containing netarsudil. The recommended dosage is one drop in the affected eye(s) once daily in the evening.[1]

1.2. Disease background

Glaucoma is a chronic, progressive condition of the eye. Glaucoma and ocular hypertension can cause increased pressure in the eye, known as elevated intraocular pressure, which is an important known risk factor for visual field loss. The increased pressure causes damage to the optic nerve, ultimately resulting in irreversible visual impairment. Primary open-angle glaucoma is the most common type of glaucoma, accounting for approximately 74% of glaucoma cases worldwide.[2, 3]

1.3. Company proposed position

The submitting company has requested that netarsudil plus latanoprost is restricted for use in patients for whom treatment with a prostaglandin analogue alone provides insufficient IOP reduction, only if:

- the patient has then tried a fixed-dose combination treatment and it has not sufficiently reduced IOP, or
- a fixed-dose combination treatment containing beta-blockers is unsuitable.

1.4. Treatment pathway and relevant comparators

The aim of treatment is to lower intraocular pressure and maintain visual function. Treatment options include surgery (laser trabeculoplasty) and eye drops. First-line eye drops are typically prostaglandin analogues such as latanoprost or bimatoprost. If these do not adequately reduce intraocular pressure, then a second medicine can be added in. These include beta-blockers (for example, timolol maleate), carbonic anhydrase inhibitors (for example, brinzolamide or dorzolamide) or sympathomimetics (for example, apraclonidine or brimonidine tartrate). For convenience, most patients who require dual therapy use a fixed-dose combination eye drop that contains two active ingredients. Commonly used fixed-dose combinations include bimatoprost plus timolol, brimonidine plus timolol, brinzolamide plus brimonidine, brinzolamide plus timolol, dorzolamide plus timolol, latanoprost plus timolol, tafluprost plus timolol or travoprost plus timolol.[2, 3]

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence to support the efficacy and safety of netarsudil plus latanoprost for the treatment of elevated intraocular pressure in adult patients with primary open-angle glaucoma or ocular hypertension comes from MERCURY 3. Details are summarised in Table 2.1.

Table 2.1. Overview of relevant studies[4-6]

Criteria	MERCURY 3
Study design	Randomised, double-blind, non-inferiority phase III study.
Eligible patients	• Aged ≥18 years. • Diagnosis of OAG or ocular hypertension (OHT) in both eyes (or OAG in one eye and OHT in the other). • Patients insufficiently controlled by their existing treatment (medicated IOP ≥17 mmHg in at least one eye and <28 mmHg in both eyes at screening) and/or considered in need for combination therapy by the investigators. • Unmedicated (postwashout) IOP >20 mmHg in at least one eye and <36 mmHg in both eyes at two qualification visits at 08:00 hours, 2 to 7 days apart. At the second qualification visit, IOP >17 mmHg in at least one eye and <36 mmHg in both eyes at 10:00 and 16:00 hours. • Best corrected visual acuity +1.0 logMAR or better by ETDRS criteria in each eye (equivalent to 20/200 or better Snellen visual acuity in each eye).
Treatments	Netarsudil 0.02%/latanoprost 0.005% (n=218) or bimatoprost 0.03%/timolol 0.5% (n=212), both administered as one drop once daily in each eye in the evening between 20:00 and 22:00 hours, for approximately 180 days following washout. Intermittent use of OTC artificial tear lubricant products was permitted, to be taken at least 10 minutes before study medication.
Randomisation	Patients were randomised equally. Randomisation was stratified by study site and maximum baseline IOP (<25 mmHg versus ≥25 mmHg).
Primary outcome	Mean IOP at 08:00, 10:00 and 16:00 hours at week 2, week 6 and month 3. The study was designed to establish non-inferiority of netarsudil plus latanoprost versus bimatoprost plus timolol, defined as a difference in IOP of ≤1.5 mmHg at all time points and ≤1.0 mmHg at five or more time points through month 3. If the upper limit of the 95% CI around the difference was below the prespecified margin, then non-inferiority was established.
Secondary outcomes	The following secondary outcomes were assessed at each time point: diurnal IOP; change from diurnally adjusted baseline IOP at each study time point; change from baseline in mean diurnal IOP; percent change from diurnally adjusted baseline IOP; percentage change from baseline in mean diurnal IOP; and the percentage of patients achieving a prespecified mean, mean change and percentage mean change in diurnal IOP levels.
Statistical analysis	Efficacy analyses were performed in the intention-to-treat population, which included all randomised patients who had received at least one dose of study medicine. Secondary outcomes were not adjusted for multiplicity and are therefore descriptive only.

Abbreviations: CI = confidence interval; ETDRS = Early Treatment Diabetic Retinopathy Study; IOP = intraocular pressure; logMAR = logarithm of the minimum angle resolvable; OAG = open-angle glaucoma; OHT = ocular hypertension; OTC = over-the-counter.

In MERCURY 3, netarsudil plus latanoprost was non-inferior to bimatoprost plus timolol for the primary outcome, with the upper limit of the 95% confidence intervals around the difference between treatments ≤1.5 mmHg at all nine time points and ≤1.0 mmHg at six out of nine time points from week 2 to month 3. See Table 2.2 for details.

Table 2.2. Key efficacy results from MERCURY 3 (ITT population).[1, 4, 6]

		Netarsudil plus latanoprost (n=218)	Bimatoprost plus timolol (n=212)
Primary outcome: mean IOP at 08:00, 10:00, 16:00 hours at week 2, week 6 and month 3			
Week 2, 08:00 hours			
	Difference (95% CI)	**0.17 (-0.40 to 0.74)**	
Week 2, 10:00 hours			
	Difference (95% CI)	**-0.17 (-0.70 to 0.35)**	
Week 2, 16:00 hours			
	Difference (95% CI)	**-0.48 (-1.03 to 0.08)**	
Week 6, 08:00 hours			
	Difference (95% CI)	**0.88 (0.32 to 1.44)[a]**	
Week 6, 10:00 hours			
	Difference (95% CI)	**0.40 (-0.15 to 0.94)**	
Week 6, 16:00 hours			
	Difference (95% CI)	**-0.08 (-0.63 to 0.46)**	
Month 3, 08:00 hours			
	Difference (95% CI)	**0.66 (0.12 to 1.20)[a]**	
Month 3, 10:00 hours			
	Difference (95% CI)	**0.42 (-0.18 to 1.03)**	
Month 3, 16:00 hours			
	Difference (95% CI)	**0.19 (-0.38 to 0.76)**	
Secondary outcome: percentage of patients reaching prespecifed categorical treatment targets (for reduction from baseline mean diurnal IOP) at month 3			
≥40% reduction		**39%**	**44%**
≥35% reduction		**54%**	**63%**
≥30% reduction		**78%**	**84%**
≥25% reduction		**87%**	**93%**
≥20% reduction		**92%**	**95%**
Secondary outcome: mean percent change from diurnally adjusted baseline IOP from week 2 to month 6			
Week 2		**-35%**	**-35%**
Month 6		**-38%**	**-40%**

[a]p-value was statistically significant at these timepoints.

Abbreviations: CI = confidence interval; IOP = intraocular pressure; ITT = intention-to-treat; LS = least square.

2.2. Evidence to support the positioning proposed by the submitting company

Preplanned subgroup analyses of MERCURY 3 were presented by the submitting company, based on age, gender, race, country, iris colour, maximum baseline IOP value and prior ocular hypotensive medication. Of potential relevance to the submission was the prior hypotensive medication subgroup analyses, which comprised the following subgroups: prior combination therapy, prior prostaglandin monotherapy and other monotherapies. [6]

2.3. Health-related quality of life outcomes

Health-related quality of life (HRQoL) was assessed using the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25) and Short Form Health Survey Questionnaire 36 (SF-36 v2). These instruments were used at screening and at month 6. [6]

2.4. Supportive studies

MERCURY 1 and MERCURY 2 were both randomised, double-blind, superiority phase III studies conducted in the US that compared the efficacy and safety of netarsudil plus latanoprost to netarsudil monotherapy and latanoprost monotherapy in patients with open-angle glaucoma or ocular hypotension with elevated intraocular pressure. MERCURY 1 was a 12-month study (3 months efficacy and 12 months safety, with optional 2 months observation) while MERCURY 2 was a 3-month study. In each study respectively, patients were randomised equally to receive netarsudil 0.02%/latanoprost 0.005% (n=238 and n=245), netarsudil 0.02% (n=244 and n=255) or latanoprost 0.005% (n=236 and n=250), administered as one drop once daily in each eye in the evening between 20:00 and 22:00 hours. In both studies, netarsudil plus latanoprost was associated with a statistically significant reduction in mean IOP at all specified timepoints at week 2, week 6 and month 3 compared with netarsudil monotherapy and latanoprost monotherapy.[2]

2.5. Indirect evidence to support clinical and cost-effectiveness comparisons

In the absence of direct evidence versus relevant comparators, the submitting company performed an indirect treatment comparison (ITC). This has been used to support the use of a cost-minimisation analysis in the economic case. See Table 2.3 for details.

Table 2.3: Summary of indirect treatment comparison

Criteria	Overview
Design	Network meta-analysis (NMA).
Population	Adult patients with primary open-angle glaucoma (OAG) or ocular hypotension (OHT).
Comparators	Fixed-dose combination (FDC) treatments including: bimatoprost plus timolol, travoprost plus timolol, latanoprost plus timolol, brimonidine plus timolol, dorzolamide plus timolol and brinzolamide plus brimonidine. Monotherapies were also included in order to form a connected network (including brimonidine, brinzolamide, netarsudil and latanoprost).
Studies included	Ten studies (base case NMA) and nine studies (sensitivity analysis).
Outcomes	Percentage change in diurnal intraocular pressure (IOP) from baseline.
Results	There was no evidence of a difference in efficacy between netarsudil plus latanoprost and most FDC comparators, and differences in treatment effects were generally small.

*Other data were also assessed but remain confidential.**

3. Summary of Safety Evidence

In the MERCURY 3 study, any ocular adverse event (AE) was reported by 60% (131/218) and 30% (64/212), and non-ocular AEs were reported by 32% (69/218) and 35% (75/212) in the netarsudil plus latanoprost and bimatoprost plus timolol group respectively. Of all reported AEs, 55% of netarsudil plus latanoprost patients and 25% of bimatoprost plus timolol patients reported ≥1 treatment-related treatment-emergent AEs-. In each group respectively, serious AEs were reported in 3.2% versus 3.3% (none of which were considered treatment-related) and the proportion of patients that discontinued the study due to an AE was 20% versus 1.9%.[4, 6]

The most frequently reported treatment-related ocular treatment-emergent AEs in the netarsudil plus latanoprost group versus the bimatoprost plus timolol group were: conjunctival hyperaemia (31% versus 9.0%), cornea verticillata (11% versus 0%), eye pruritus (7.8% versus 0.9%), punctate keratitis (5.5% versus 1.9%) and allergic conjunctivitis (5.0% versus 0.5%).[4]

The safety profile of netarsudil plus latanoprost appears to be less favourable than that of bimatoprost plus timolol, however, AEs were generally mild or moderate in severity and often resolved spontaneously. The preservative benzalkonium chloride that is present in the netarsudil plus latanoprost eye drop is also known to contribute to ocular adverse reactions and it is difficult to quantify its effect. Further long-term data are awaited to fully characterise the safety profile of netarsudil plus latanoprost.[2, 4]

*Other data were also assessed but remain confidential.**

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- MERCURY 3 was a randomised, double-blind, phase III study that compared netarsudil plus latanoprost with a commonly prescribed relevant comparator, bimatoprost plus timolol.
- Netarsudil plus latanoprost was non-inferior to bimatoprost plus timolol for the primary outcome, mean IOP, with the upper limit of the 95% confidence intervals around the difference between treatments ≤1.5 mmHg at all nine time points and ≤1.0 mmHg at six out of nine time points from week 2 to month 3. Although a surrogate outcome, IOP is considered predictive of longer-term, clinically relevant complications, such as optic nerve damage and visual field loss.[2]

4.2. Key uncertainties

- There is uncertainty in the magnitude of benefit for disease progression associated with netarsudil plus latanoprost in the long-term. The primary outcome of MERCURY 3 measured IOP until month 3, and the study was stopped after approximately 6 months. This is particularly relevant given that glaucoma is a chronic, progressive condition that requires long-term treatment. Furthermore, the European Medicines Agency (EMA) noted that longer-term efficacy may be overestimated due to the lower completion rates for netarsudil plus latanoprost compared with latanoprost monotherapy and the imputation

methods used for missing data in the MERCURY 1 study. In MERCURY 3, discontinuation rates due to AEs were higher in the netarsudil plus latanoprost group and therefore the relative treatment effect compared with bimatoprost plus timolol may also be overestimated.[2, 4]

- Subgroup analysis that supports the proposed positioning was not presented in the company's submission. Preplanned subgroup analysis included prior hypotensive medication experience, however the relative treatment effect of netarsudil plus latanoprost in the proposed positioning population is uncertain.
- The overall study population of MERCURY 3 is not reflective of the patients that are likely to receive netarsudil plus latanoprost in Scottish clinical practice as per the proposed positioning. A limited number of patients had prior prostaglandin analogue monotherapy treatment or prior combination treatment; 26% of the study population had not previously received a prostaglandin analogue. Patients who had a known hypersensitivity or contraindication to beta-blockers were excluded from the study. Therefore, there are potential generalisability issues with the overall study population results. In addition, there were notable differences in two baseline characteristics between treatment groups: proportion of female patients (60% versus 43%) and prior prostaglandin analogue use (78% versus 69%).[4, 6]
- The ITC had some limitations. The target population was broader than the proposed positioning; the ITC did not include tafluprost plus timolol which is a relevant comparator; there was a lack of clarity around study inclusion for monotherapy studies; the results had wide credible intervals suggesting uncertainty; the outcome evaluated was percentage change in diurnal intraocular pressure which meant the company had to derive some values from studies that did not present these data; and, safety and HRQoL outcomes were not assessed. Despite these limitations, the submitting company's conclusion of similar efficacy to relevant comparators seems reasonable. .

4.3. Clinical expert input

Clinical expert input obtained by SMC suggests that netarsudil plus latanoprost would be a useful additional treatment option to treat elevated intraocular pressure. Eye drops containing beta-blockers may be unsuitable in a considerable number of patients, and there are limited options in these cases.

4.4. Service implications

There are no major service implications anticipated with the introduction of netarsudil plus latanoprost.

*Other data were also assessed but remain confidential.**

5. Summary of Patient and Carer Involvement

No patient group submission was received.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

The submitting company presented an economic case, summarised in Table 6.1.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-minimisation analysis.
Time horizon	One year.
Population	The population entering the model comprised adult patients with primary open-angle glaucoma (POAG) or OHT for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction.
Comparators	The comparators to netarsudil plus latanoprost were topical eye drop FDCs. These were: bimatoprost plus timolol, brimonidine plus timolol, brinzolamide plus brimonidine, brinzolamide plus timolol, dorzolamide plus timolol, latanoprost plus timolol, tafluprost plus timolol, and travoprost plus timolol. The analysis included a selection of branded medicines and their generics (if available) within each of the FDCs. In total, 22 comparators were used in the analysis.
Model description	A Markov state transition model was used, comprising four health states. These were: IOP reduction from baseline less than 20%, IOP reduction from baseline 20% to 30%, IOP reduction from baseline greater than 30%, and death. Patients entered the model in the IOP reduction from baseline less than 20% health state, where they initiated treatment with either netarsudil plus latanoprost or one of the comparator treatments. While on treatment, patients could transition between any of the IOP health states, based on their percentage reduction in IOP from baseline. Patients could enter the death state from any IOP health state.
Clinical data	Clinical efficacy data were drawn from MERCURY 3 and the NMA.[4, 6] AEs of any severity that occurred in at least 5% of patients in the netarsudil plus latanoprost arm of the MERCURY 3 study or in any of the relevant arms of the comparator studies were included.
Extrapolation	Based on the results from the NMA netarsudil plus latanoprost and the comparators were assumed to have similar efficacy. Therefore, the model transition probabilities derived from MERCURY 3 were identical for all treatments. As POAG and OHT were not expected to have a direct impact on the life expectancy of patients, only general population mortality was applied to the model cohort.[7]
Quality of life	Given the cost-minimisation analysis no utility values were applied in the economic analysis.
Costs and resource use	Medicine acquisition and adverse event costs were included. The comparators' acquisition costs were costed with a mix of BNF drug tariff prices (for generic medicines) and BNF NHS indicative prices (for branded medicines). Scottish drug tariff prices were comparable to the BNF drug tariff prices included in the economic case and are not expected to impact the analysis. Administration costs were assumed negligible given the self-administration of FDCs. Health state costs were excluded as transition probabilities, and therefore health state occupancy, were equal between netarsudil plus latanoprost and all comparators. Thus, there would be no difference in health state costs between each treatment if these were included.
PAS	There are no Patient Access Scheme (PAS) discounts in place for netarsudil plus latanoprost or comparators.

6.2. Results

Table 6.2 shows the base case results versus the 22 comparators.

Table 6.2: Base case results

Medicine [brand name if appropriate]	Acquisition costs per patient per year (£)
latanoprost 50micrograms/mL / netarsudil 200micrograms/mL [Roclanda]	130
bimatoprost 300micrograms/mL/ timolol 5mg/mL eye drops	53
dorzolamide 20mg/mL / timolol 5mg/mL eye drops	56
latanoprost 50micrograms/mL / timolol 5mg/mL eye drops	62
travoprost 40micrograms/mL / timolol 5mg/mL eye drops	63
dorzolamide 20mg/mL / timolol 5mg/mL eye drops preservative free [Eylamdo]	105
dorzolamide 20mg/mL / timolol 5mg/mL eye drops preservative free [Vizidor Duo]	106
brinzolamide 10mg/mL / timolol 5mg/mL eye drops	120
brimonidine 2mg/mL / timolol 5mg/mL eye drops [Combigen]	117
brinzolamide 10mg/mL / brimonidine 2mg/mL eye drops [Simbrinza]	120
dorzolamide 20mg/mL / timolol 5mg/mL eye drops [Cosopt]	130
brimonidine 2mg/mL / timolol 5mg/mL eye drops [Combigan]	130
brinzolamide 10mg/mL / timolol 5mg/mL eye drops [Azarga]	143
latanoprost 50micrograms/mL / timolol 5mg/mL eye drops 0.2mL unit dose preservative free [Fixapost]	163
dorzolamide 20mg/mL / timolol 5mg/mL eye drops preservative free [Cosopt iMulti]	167
tafluprost 15micrograms/mL / timolol 5mg/mL eye drops 0.3mL unit dose preservative free [Taptigom]	176
travoprost 40micrograms/mL / timolol 5mg/mL eye drops [DuoTrav]	181
bimatoprost 300micrograms/mL / timolol 5mg/mL eye drops preservative free [Eyzeetan]	184
bimatoprost 300micrograms/mL / timolol 5mg/mL eye drops preservative free [Ganfort]	184
latanoprost 50micrograms/mL / timolol 5mg/mL eye drops [Xalacom]	186
bimatoprost 300micrograms/mL / timolol 5mg/mL eye drops 0.4mL unit dose preservative free [Ganfort]	217
dorzolamide 20mg/mL / timolol 5mg/mL eye drops 0.2mL unit dose preservative free	223
dorzolamide 20mg/mL / timolol 5mg/mL eye drops 0.2mL unit dose preservative free [Cosopt]	346

Abbreviations: mL = millilitre; mg = miligram

6.3. Sensitivity analyses

A range of sensitivity and scenario analyses were considered and descriptions of these key scenarios are provided in table 6.3 below. The most impactful scenario was applying BNF drug tariff prices to all medicines.

Table 6.3: Summary of scenario analysis results

	Parameter	Base case	Scenario
1a	Medicine prices	BNF drug tariff prices (for generics) and BNF NHS indicative prices (for branded medicines).	BNF NHS indicative prices (for all medicines)
1b			BNF drug tariff prices (for all medicines)
2	Adverse event costs	Included	Excluded
3	Wastage	Included	Excluded

Abbreviations: BNF = British National Formulary.

6.4. Key strengths

- Transition probabilities in the model were drawn from a phase III randomised controlled study- MERCURY 3.
- Clear calculations of medicine acquisition input costs were presented in the economic model.

6.5. Key uncertainties

- There was uncertainty in the medicine acquisition costs used in the base case, with the use of BNF drug tariff prices for generic medicines and BNF NHS indicative prices for branded medicines. As comparator medicines are more likely to be prescribed in primary care, the BNF drug tariff prices are likely to be more appropriate. Scenario analysis was available to show that under BNF drug tariff prices for all comparator medicines, comparator medicine acquisition costs fell, and the base case cost-saving conclusions versus selected comparators were subject to uncertainty. However, the levels of incremental costs were often small throughout the analyses.
- There were limited comparators in the economic analysis when considering part of the positioning, that of netarsudil plus latanoprost to be considered as treatment if an FDC treatment containing beta-blockers is unsuitable. As several comparator combinations contained timolol, a type of beta-blocker, only brinzolamide plus brimonidine remained relevant. SMC experts also highlighted that patients in this group are likely to be treated with two single-active ingredient eye drops. However, estimates of the costs of two single-active ingredient eye drops suggested comparable costs to the FDCs considered in the model.
- Economic subgroup analyses on the parts of product positioning were not presented. Whilst these subgroup results would be unlikely to impact the economic results, given results are 12-months of primarily medicine acquisition costs, the lack of clinical subgroup data increases uncertainty in the assumption of similar efficacy across all treatments in the proposed positioning. However, the evidence suggesting similar efficacy in the broader population, use of a cost-minimisation approach, and the use of a 12-month time horizon, may ease these uncertainties regarding economic subgroup analyses.

- There were uncertainties in how the model captured disease progression in POAG or OHT. The model structure relied on IOP reductions and was noted as aligning with the model of NICE guideline 81 (NG81), but the NG81 economic model included later glaucoma severity health states which were not developed as part of the submitting company's model.[3] In addition, given IOP health state transitions were two-way, this presents uncertainty as it implies that vision loss from glaucoma is reversible. However, these economic model limitations were not impactful given the cost-minimisation approach and assumptions of equivalence in efficiency amongst all treatments in the model.

7. Conclusion

After considering all the available evidence, the Committee was able to accept netarsudil plus latanoprost for use in NHSScotland.

8. Guidelines and Protocols

The Scottish Intercollegiate Guidelines Network (SIGN) published "Glaucoma referral and safe discharge: A national clinical guideline" (SIGN 144) in March 2015, which was revalidated in April 2018.[8]

The National Institute for Health and Care Excellence (NICE) published "Glaucoma: diagnosis and management" (NG81) in November 2017, which was last updated in January 2022.[3]

The European Glaucoma Society (EGS) published "Terminology and Guidelines for Glaucoma (5th edition)" in 2020.[9]

9. Additional Information

9.1. Product availability date

June 2023

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year
Netarsudil plus latanoprost	**One drop in the affected eye(s) once daily in the evening**	**£146**

Costs from BNF online on 04 November 2024. Usage has been estimated on the basis of 20 drops per mL, however drop sizes may vary. Costs assume both eyes are being treated.

10. Company Estimate of Eligible Population and Estimated Budget Impact

The submitting company estimated there would be 15,965 patients eligible for treatment with netarsudil plus latanoprost in year 1, rising to 16,129 patients in year 5 to which confidential uptake rates were applied.

SMC is unable to publish the budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget impact.

*Other data were also assessed but remain confidential.**

References

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(SIGN publication no. 144). [March 2015]. Available from URL: http://www.sign.ac.uk.
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This assessment is based on data submitted by the applicant company up to and including **13 December 2024.**

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive

access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.