Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Latanoprost–netarsudil for previously treated primary open-angle glaucoma or ocular hypertension [NICE TA 1009]		
Available at	**https://www.nice.org.uk/guidance/ta1009**		
Date of issue	02 October 2024	**Implementation deadline**	3 months [02 January 2025]

Medicine details	
Name and brand name	Latanoprost – netarsudil (Roclanda)
Manufacturer	Santen
Mode of action	Both components lower Intraocular Pressure (IOP) by increasing the outflow of aqueous humor. Although both latanoprost and netarsudil lower IOP by increasing aqueous humor outflow, their mechanisms of action are different.
Licenced indication	**Therapeutic indications** Roclanda is indicated 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.
Formulation	Eye drop solution (2.5ml)
Dosage	**Posology** Use in adults, including the elderly The recommended dosage is one drop in the affected eye(s) once daily in the evening. Patients should not instill more than one drop in the affected eye(s) each day. If one dose is missed, treatment should continue with the next dose in the evening. **NB: The safety and efficacy of Roclanda in children below the age of 18 years have not been established.**
Comparison of NICE TA with Summary of Product Characteristics (SmPC)	For the NICE evaluation, 'the company asked for latanoprost–netarsudil to be considered only after a fixed-dose combination treatment has not worked well enough or when a fixed-dose combination treatment with a beta-blocker is unsuitable'[1].

[1] www.medicines.org.uk

	Note that in the license, latanoprost-netarsudil should be used in patients for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.

NICE TA recommendations

Recommendations

1. Recommendations

1.1. Latanoprost–netarsudil is recommended as an option for reducing intraocular pressure (IOP) in adults with primary open-angle glaucoma or ocular hypertension when a prostaglandin analogue alone has not reduced IOP enough, only if:

- they have then tried a fixed-dose combination treatment and it has not reduced IOP enough, or
- a fixed-dose combination treatment containing beta-blockers is unsuitable.

MRU comments: See front cover for comments by specialists

1.2. This recommendation is not intended to affect treatment with latanoprost–netarsudil that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

Why the committee made these recommendations

Usual treatment for reducing IOP in people with primary open-angle glaucoma or ocular hypertension includes a prostaglandin analogue eye drop (for example, bimatoprost or latanoprost). If this does not work well enough, people usually have a fixed-dose combination treatment eye drop. These include combinations of a prostaglandin analogue with a beta-blocker (for example, bimatoprost–timolol), or a prostaglandin analogue with carbonic anhydrase inhibitors or sympathomimetics.

Latanoprost–netarsudil is a fixed-dose combination treatment containing a prostaglandin analogue with a Rho kinase inhibitor. For this evaluation, the company asked for latanoprost–netarsudil to be considered only after a fixed-dose combination treatment has not worked well enough or when a fixed-dose combination treatment with a beta-blocker is unsuitable.

Clinical trial evidence suggests that latanoprost–netarsudil is as effective as bimatoprost–timolol. Indirect comparisons of latanoprost–netarsudil with other fixed-dose combination treatments are highly uncertain but suggest that they have similar effectiveness.

A cost comparison suggests that latanoprost–netarsudil has similar or lower costs than most branded fixed-dose combination treatments. These are usually used after a fixed-dose combination treatment has not reduced IOP enough. Latanoprost–netarsudil also has similar or lower costs compared with some generic fixed-dose combination treatments. So, latanoprost–netarsudil is recommended.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned an implementation deadline of 3 months The implementation deadline is 02 January 2025

Clinical effectiveness

- Clinical trial evidence suggests that latanoprost–netarsudil is as effective as bimatoprost–timolol. Indirect comparisons of latanoprost–netarsudil with other fixed-dose combination treatments are highly uncertain but suggest that they have similar effectiveness.

Patient safety

- The product should be used within its product licence.
- ▼ This is a Black Triangle drug – this medicinal product is subject to reporting of all suspected adverse drug reactions to the MHRA. This will allow timely identification of new safety information.
- There are no additional safety concerns identified outside those already recognised and described in BNF / SPC.

Patient factors

- An additional treatment option would be valued by patients. Most combinations of treatments used for Glaucoma, contain a beta clocker (timolol) and so this new product may be useful for those 'people for whom beta-blockers are contraindicated or not suitable'.[2]
- Patients would need to be reviewed on a regular basis by the prescribing clinician to ensure concordance, monitor for adverse effects and efficacy.
- Using a combination product will limit the number of drops required on a daily basis.
- Note: There is no preservative free option available.
- NICE NG81 Glaucoma: diagnosis and management www.nice.org.uk/guidance/ng81 recommends preservative-free formulations for:
    - Those with an allergy to preservatives
    - Those with clinically significant and symptomatic ocular surface disease, at high risk of conversion to chronic open angle glaucoma (COAG)
- **www.glaucoma.co.uk**
    - Glaucoma and Dry Eye commonly appear together. Studies suggest that 50-60% of people who are being treated for glaucoma, also have dry eye disease.
    - This product contains the preservative benzalkonium chloride.
    - People with severe dry eyes who also have glaucoma may not be suitable for treatment with latanoprost-netarsudil (Rolanda®).
- Due to netarsudil's vasodilating properties, other eye drops should be administered before latanoprost + netarsudil. Eye ointments should be administered last[1].
- Contact lenses should be removed prior to instillation of latanoprost + netarsudil and may be reinserted 15 minutes following its administration[1].

Environmental impact

- Additional packaging will be generated and will be an environmental impact with regards to waste management.

Equality & diversity

Equality[2]

- Stakeholders noted that the risk of glaucoma differs between ethnic groups. The committee was not provided with any evidence for latanoprost–netarsudil for separate ethnic groups. It concluded that no adjustments to the recommendation were needed. Stakeholders also noted that once-daily treatments may reduce inequalities by providing a simpler treatment regimen for people or their carers who may have challenges with using multiple eye drops. They also noted that some additives such as preservatives can cause intolerance in people with cornea damage. The committee further concluded that patients and clinicians should take these issues into account when considering latanoprost–netarsudil, but that no adjustments to the recommendation were needed.

Note 1: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-

[2] www.nice.org.uk

medicines-for-children-specialised-services/ and a Blueteq form is available.

Place in therapy relative to available treatments

NICE Clinical Knowledge Summaries[3]

- Mild Ocular hypertension – No treatment is required. Only monitoring
- If treatment is recommended, then 1st line treatment is 360^0 selective laser trabeculoplasty (SLT).
- If SLT is not successful or not suitable then a generic prostaglandin analogue eye drop should be offered. (for example, latanoprost, travoprost, bimatoprost or tafluprost)
- If a first-line treatment is unsuccessful, or not tolerated, second-line treatment options that may be considered by the ophthalmologist which include:
    - A generic prostagladin analogue (PGA).
    - Switching to an alternative generic PGA.
    - A topical beta-blocker.
    - Switching to, or adding in, a second-line drug treatment, which are: a non-generic PGA, a topical sympathomimetic, a topical carbonic anhydrase inhibitor, a topical miotic **or a combination of treatments.**
- Lifetime monitoring is routine once treatment is commenced.
- Visual summary available from NICE (page 8 below) following the publication of the NICE guidance for Glaucoma – diagnosis and management (January 2022) https://www.nice.org.uk/guidance/ng81

Stakeholder views

The paper was sent out for consultation and comments are listed on the front sheet.

Cost-effectiveness

Section 1: cost of the technology

Annual cost per patient (or complete course if shorter)

- The list price for latanoprost–netarsudil is £10.00 per 2.5-ml bottle (excluding VAT; company submission, April 2024, subject to approval).
- Costs may vary in different settings because of negotiated procurement discounts
- Costs in primary care & secondary care: £10/ eye drop bottle (2.5ml)
  Costs in secondary care: Confirmed by formulary pharmacists

Assuming that treatment for Glaucoma in both eyes is anticipated, one bottle per month could be requested by patients. - £120 year

- ***NICE estimate 15 bottles per year (in the resource impact template) could be used annually which could be considered an over estimation.***

Availability of CAP/PAS price:

- No

Price relative to comparable medicines:

Preparation	Pack size	DT price*	Class
Latanoprost & Timolol	2.5ml	£3.73	PROSTAGLANDINE & BETA BLOCKER
Dorzolamide & Timolol	5ml	£3.96	CARBONIC ANHYDRASE INHIBITOR & BETA BLOCKER
Travoprost & Timolol	2.5ml	£5.02	PROSTAGLANDINE & BETA BLOCKER
Brinzolamide & Timolol	5ml	£8.47	CARBONIC ANHYDRASE INHIBITOR

[3] www.cks.nice.org.uk/topics/glaucoma

			& BETA BLOCKER
Brinzolomide & Brimonidine	5ml	£9.23	CARBONIC ANHYDRASE INHIBITOR & SYMPATHOMIMETIC
Latanoprost & Netarsudil	2.5ml	£10.00	PROSTAGLANDINE & RHO KINASE INHIBITOR
Bimatoprost & Timolol	3ml	£10.16	PROSTAMIDE & BETA BLOCKER
Brimonidine & Timolol	5ml	£15.71	SYMPATHOMIMETIC & BETA BLOCKER

*November 2024 Drug Tariff accessed on 1st November 2024]

Section 2: NICE resource impact statement and template

NICE estimated eligible population expected to receive latanoprost – netarsudil over the course of the next 5 years [NICE Resource Template], in Surrey Heartlands ICB

Eligible population and uptake	Current practice	Future practice - year 1	Future practice - year 2	Future practice -year 3	Future practice - year 4	Future practice - year 5
Eligible population	2,937	2,965	2,994	3,023	3,052	3,081
Latanoprost-netarsudil	0%	1%	2%	3%	4%	5%
People choosing latanoprost-netarsudil	0	30	60	91	122	154

NICE resource impact statement

- NICE expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 57.1 million people)[2].
- This is because the technology is a further treatment option and there are a number of options available.

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

Recommended traffic light status and rationale:

Place in therapy

- 2nd line treatment option in line with NICE
- when a prostaglandin analogue alone has not reduced IOP enough, only if:
  - they have then tried a fixed-dose combination treatment and it has not reduced IOP enough, or
  - a fixed-dose combination treatment containing beta-blockers is unsuitable.

- **BLUE (with no information sheet)** on the traffic light system and at least 1 month supply should be supplied at initiation before transfer of care.

Implementation

Actions to implement:

Primary care

- Continue to prescribe treatment as recommended by the specialist team.
- Patients would need to be reviewed on a regular basis by the prescribing clinician

to ensure concordance and monitor for adverse effects.
- Prescribe generically following transfer of care from ophthalmologist
- Stop treatment only on the recommendation of a specialist

Secondary care
- Patients would need to be reviewed on a regular basis by the specialist team for monitoring of efficacy.
- Trusts to follow internal governance procedures to add to their formulary
- Prescribe generically at discharge and provide clear information about treatment expectations to primary care prescriber.

ICS
- This technology is commissioned by Surrey Heartlands ICB who are required to comply with the recommendation in the NICE TA within the time set in the publication.

PAD and Joint Formulary
- New PAD profile will be required

Proposed tick box forms
N/A

References:

1 Summary of Product Characteristics. emc. Available at: www.medicines.org.uk Accessed <12/11/2024>

2 NICE Technology Appraisal Guidance: . Available at: www.nice.org.uk Accessed <12/11/2024>

3 NICE Resource Impact Report: . Available at: https://www.nice.org.uk/guidance/ta1009/resources Accessed <12/11/2024>

4 NICE Resource Impact Template: . Available at: https://www.nice.org.uk/guidance/ta1009/resources Accessed <12/11/2024>

Declaration of interest:

	Name	**Role**	**Date**	**Declaration of interests (please give details below)**
Prepared by	Clare Johns	Lead Pharmacy Technician – Medicines Resource Unit	October 24	None
Supported by	Glaucoma Specialist teams	Local Trusts	November 2024	
Reviewed by				