

## Further Update on Proposed USA Medicare Changes

### Highlights

- **Local coverage determination (LCD) changes for Medicare reimbursement of minimally invasive glaucoma surgery (MIGS) procedures in the USA have been proposed by an additional four Medicare Administrative Contractors (MACs).**
- **Approximately 40% of the Company's global revenues, are derived from health care facilities located in the thirty-eight (38) states covered by these four MACs.**
- **Reimbursement coverage for the Company's Molteno3® portfolio will remain unaffected.**
- **Total USA sales for the four months ended 31 October 2023 were US\$3.34 million, up 74% compared with the previous corresponding period (PCP).**
- **Should the LCD changes be implemented, some of the Company's customers may lose reimbursement coverage for canaloplasty procedures from December 24, 2023, onwards, which is expected to negatively impact the Company's sales in the short term.**
- **The Company intends to pursue all remediation possibilities to reinstate coverage for canaloplasty.**
- **Program of near-term initiatives designed to overcome the challenges imposed by the proposed LCD changes is expected to reduce the impact on sales revenue in the medium to long term.**

Nova Eye Medical Limited (ASX: EYE) (**Nova Eye Medical** or the **Company**), today comments on the final drafts of the local coverage determinations (LCDs) issued by an additional four MACs. The LCD changes relate to local coverage policies for minimally invasive glaucoma surgery (MIGS) procedures and follow the issuance of a final draft LCD by one MAC as announced to the market on October 31, 2023.

The iTrack™ device secured clearance from the USA Food and Drug Administration (FDA) in 2008, with canaloplasty granted a permanent Category 1 Current Procedural Terminology (CPT) code by Centre for Medicare Services (CMS). The CPT code has been the basis for reimbursement for canaloplasty procedures in the USA for over a decade and iTrack™ has been used in more than 150,000 canaloplasty procedures globally.

Despite its established clinical history, in their current determination the MACs have categorised canaloplasty as "investigational" for Medicare-insured patients and hence not

eligible for reimbursement.

The Company convened a meeting of practicing glaucoma surgeons and faculty members of leading academic institutions in the USA at the recent American Academy of Ophthalmology (AAO) to discuss the proposed LCD changes. Based on the consensus reached, the Company strongly disagrees with the non-coverage determination proposed by the LCDs.

The Company intends to engage with the MACs to address what the Company believes are fundamental procedural issues with the LCD changes and to provide additional clinical data to support the continued coverage of canaloplasty procedures.

In total, five MACs have now issued final draft LCDs proposing to restrict or deny coverage for some MIGS procedures. Approximately 40% of the Company’s global revenues, including both iTrack™ and Molteno3®, are derived from health care facilities located in the thirty-eight (38) states covered by these five MACs.

Underpinned by the launch of the iTrack™ Advance device, the Company recorded a strong sales result in the USA for the four months ended 31 October 2023 of US\$3.34 million, representing a significant sales increase of 74% compared with the previous corresponding period (PCP).

In the short term, the biggest challenge associated with the LCD changes is the expected customer confusion and misinformation in the marketplace, leading to a reduction in sales. However, the Company has a program of near-term initiatives designed to overcome the challenges imposed by the proposed LCD changes, thus reducing the expected impact on sales revenue in the medium to long term.

***This release dated 14th November 2023 has been authorised for lodgement to ASX by the Board of Directors of Nova Eye Medical Limited and lodged by Simon Gray, Company Secretary.***

– ENDS –

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**ABOUT NOVA EYE MEDICAL**

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons s globally, these technologies include iTrack™ minimally invasive glaucoma surgery

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(MIGS), a consumable surgical device that restores the eye's natural outflow pathway to lower pressure inside the eye and to eliminate patient reliance on anti-glaucoma medications for mild-moderate glaucoma. The Molteno3<sup>®</sup> glaucoma drainage device platform is designed to enhance surgical utility and optimize clinical outcomes for long-term IOP control in cases of severe glaucoma. It also offers the benefit of a simplified and faster surgical procedure. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by a global network of distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

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For additional information about Nova Eye Medical and its technologies, please visit: [www.nova-eye.com](http://www.nova-eye.com)