# Minimally Invasive Bleb Surgery for Glaucoma

## Recommendation

January 2024



## **Final Recommendation**

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding minimally invasive bleb surgery for glaucoma.

## **Rationale for the Recommendation**

The Ontario Health Technology Advisory Committee made the above recommendation after considering the clinical, economic, and patient preferences and values evidence reported in the health technology assessment.<sup>1</sup>

The clinical evidence supports that minimally invasive bleb surgery (MIBS) results in clinically meaningful intraocular pressure (pressure in the eye, or IOP) reduction and less antiglaucoma medication (e.g., eye drops) required post-surgery, but it is uncertain if MIBS results in similar outcomes to trabeculectomy (conventional/incisional glaucoma surgery). However, MIBS may be safer than trabeculectomy and result in fewer short-term adverse events, as well as follow-up visits and interventions. Clinically significant IOP reduction and fewer eye drops required were important outcomes to patients and health care providers. While the cost-effectiveness of MIBS was not estimated because of limitations in the available data, there was consensus that the estimated total cost of \$1.93 million over the next 5 years to publicly fund MIBS is reasonable.

The committee highlighted the uncertainty in long-term device durability and acknowledged the lack of long-term effectiveness data for MIBS. In particular, the committee noted that people who receive MIBS may require future reintervention due to glaucoma disease progression. Minimally invasive bleb surgery was recognized as a less invasive treatment alternative for people with moderate to severe (advanced) glaucoma, for which no other minimally invasive option currently exists.

The committee advises that the Ontario Health Provincial Vision Task Force support the adoption of clinical best practices for the use of MIBS to guide implementation. The committee also noted that long-term data collection on MIBS is needed to assess its long-term effectiveness.

## Decision Determinants for Minimally Invasive Bleb Surgery for Glaucoma

#### **Overall Clinical Benefit**

#### **Effectiveness**

How effective is the health technology/intervention likely to be (taking into account any variability)?

Minimally invasive bleb surgery results in clinically meaningful IOP reduction and a reduction in antiglaucoma medication used post-surgery, but we are uncertain if MIBS results in similar outcomes as conventional/incisional glaucoma surgery (e.g., trabeculectomy). Grading of Recommendations Assessment, Development, and Evaluation (GRADE): Moderate (based on evidence from randomized controlled trials) to Very low (based on evidence from comparative observational studies), for both outcomes. Compared with conventional/incisional glaucoma surgery, MIBS may result in improved health-related quality of life, along with fewer follow-up visits, adverse events, and follow-up interventions (GRADE: Moderate to Very low). MIBS may also reduce IOP and the number of antiglaucoma medications used compared with other glaucoma treatments, but the evidence is very uncertain (GRADE: Very low).

#### Safety

How safe is the health technology/intervention likely to be?

Compared with conventional/incisional glaucoma surgery, MIBS may result in fewer adverse events. GRADE: Moderate (based on evidence from randomized controlled trials) to Very low (based on evidence from comparative observational studies).

#### **Burden of Illness**

What is the likely size of the burden of illness pertaining to this health technology/intervention?

Glaucoma affects about 2.5% Canadians, and there are an estimated 323,000 people in Ontario who have glaucoma in 2023.

#### Need

How large is the need for this health technology/intervention?

MIBS is a surgical procedure that is less invasive than conventional/incisional glaucoma surgery (e.g., trabeculectomy). MIBS may be a treatment option for people who cannot or do not wish to undergo conventional/incisional glaucoma surgery, or who want to delay or replace the need for conventional/incisional glaucoma surgery.

#### **Patient Preferences and Privacy**

#### **Patient Preferences and Values**

Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment?

Participants reported desiring effective treatments for glaucoma to prevent blindness. Patients valued the independence and quality of life positive eye health provides. Trust between patient and health care provider was seen as valuable for decision-making when choosing glaucoma treatments, such as glaucoma surgery.

#### Autonomy, Privacy, Confidentiality, and/or Other Relevant Ethical Principles as Applicable

Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment?

Participants reported anxiety and fear around a diagnosis of glaucoma and a desire for a safe and effective treatment (principle of beneficence). Participants reported feeling that minimally invasive glaucoma surgeries provided better health, consistent with principles of independence and empowerment.

#### **Equity and Patient Care**

#### **Equity of Access or Outcomes**

Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?

Currently MIBS is available only at some hospitals in the province that have allocated a section of their hospital global budget to fund a limited number of MIBS procedures. This creates unequal access to MIBS. In addition, people who experience financial or physical challenges to using antiglaucoma medications may not be afforded the chance of achieving the same clinical outcomes as those without these issues.

#### **Patient Care**

Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?

Minimally invasive bleb surgery provides an additional surgical alternative for people with glaucoma. Due to its less invasive nature compared with conventional/incisional glaucoma surgery, MIBS may reduce the need for subsequent patient care by reducing the number of adverse events and follow-up visits and reinterventions for people with glaucoma. In addition, there are challenges for adherence to antiglaucoma medication (e.g., eye drops); MIBS may help by lowering the number of antiglaucoma medication needed.

#### **Cost-Effectiveness**

#### **Economic Evaluation**

#### How efficient is the health technology/intervention likely to be?

We identified two directly applicable Canadian economic evaluations that found MIBS may have similar effectiveness as trabeculectomy but different costs, although these results are highly uncertain due to the lack of long-term data and uncertainty in the relative effectiveness of MIBS. We did not conduct a primary economic evaluation due to the lack of long-term clinical evidence. Therefore, the cost-effectiveness of MIBS is unknown.

#### Feasibility of Adoption Into Health System

#### **Economic Feasibility**

How economically feasible is the health technology/intervention?

We estimated that the budget impact of publicly funding MIBS would range from a budget increase of \$0.11 million in year 1 to \$0.67 million in year 5, for a total of \$1.93 million over 5 years.

#### **Organizational Feasibility**

How organizationally feasible is it to implement the health technology/intervention?

MIBS is available in the province at some hospitals. We expect that if publicly funded, there are no substantial barriers to adoption of MIBS devices in the health care system.

### Reference

(1) Ontario Health. Minimally invasive bleb surgery for glaucoma: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2024 Jan;24(1):1–151. Available from: hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-andrecommendations/minimally-invasive-bleb-surgery-for-glaucoma

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