INESSS
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XEN45 gel implant for microinvasive glaucoma surgery (MIGS)

English summary

Une production de l'Institut national
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et en services sociaux (INESSS)

Québec

SUMMARY

XEN45 gel implant for microinvasive glaucoma surgery (MIGS)

Mandate

The XEN45 gel implant is currently used in Québec's health-care system for the treatment of moderate to advanced primary open-angle glaucoma (POAG), although with a limited access. The Bureau de l'innovation (BI) gave the mandate to the Institut national d'excellence en santé et en services sociaux (INESSS) to produce a report on the advisability of expanding access to public coverage.

Evaluation process

Scientific literature data and data submitted by the manufacturer were reviewed to document the efficacy, safety, and efficiency of the XEN45 gel implant. This search was supplemented with a review of the grey literature and the gathering of contextual and experiential data through consultations with an expert committee, survey data submitted by the foundation Fighting Blindness Canada, and Québec clinical administrative data.

Health needs

Glaucoma refers to a group of chronic, progressive optical neuropathies that cause an irreversible loss of visual field (VF) and that can ultimately lead to blindness. It is the leading irreversible cause of blindness worldwide. POAG is the most common form of glaucoma.

The treatment strategy in the management of POAG is primarily aimed at reducing intraocular pressure (IOP), the most easily modifiable risk factor. In the early to moderate stages of POAG, the disease is also most often asymptomatic. The main discomfort for patients lies in the side effects of drops and their local application.

However, in the presence of rapidly progressing or later-stage (moderate to advanced) POAG, symptomatic vision loss where the glaucoma patient's peripheral VF shrinks, causing a "tunnel vision" effect, may occur.

The patients consulted also reported fearing a loss of autonomy due to the inability to read or drive a vehicle. In addition, fewer treatment options are available, and having to undergo more-invasive filtration surgery causes patients additional worries because of the potential for sometimes serious complications, including vision loss.

Additional effective and safe treatment options for delaying or avoiding more invasive surgery would be desirable.

Context of use

The XEN45 is a tubular device implanted in the sclera using a single-use injector. The mechanism of action of the XEN45 (scleral) is similar to that of trabeculectomy (invasive eye surgery). It promotes the evacuation of the aqueous humor out of the eye into a subconjunctival filtering bleb. The XEN45 gel implant is intended to reduce intraocular pressure (IOP) in patients with primary open-angle glaucoma (POAG) for whom previous medical treatments have failed.

Results

Efficacy

- According to the studies identified, XEN45 implantation leads to a reduction in IOP (of -3.5 ± NR to -7.2 ± 8.2 mm Hg) that can be maintained over the medium term (36 months). The reduction is similar to what can be achieved with its comparator, trabeculectomy (-7.3 ± NR to -10.5 ± 9.2 mm Hg).
- XEN45 implantation also reduces the number of drugs required to maintain IOP at the target level. This reduction is similar to that observed with trabeculectomy. Indeed, the patients in all groups from the studies selected were taking more than 2 classes of antiglaucoma drugs before their surgery (XEN45 or trabeculectomy). At the 12-month postoperative follow-up, this number was 0.1 ± 0.3 to 0.3 ± 0.5 for the XEN45 and 0.1 ± 0.2 to 0.2 ± 0.5 for trabeculectomy.
- No difference in visual field (36-month follow-up) or visual acuity (24-month follow-up) was observed with the use of the XEN45.

Safety

- The three most common adverse events (AEs) of low and moderate seriousness identified for both types of intervention are hyphema, choroidal detachment and hypotony. In the selected studies, similar ranges were observed for the XEN45 and trabeculectomy (0 to 24.6% and 0.6 to 30.4%, respectively). Certain serious AEs were also identified, including malignant glaucoma, endophthalmitis and retinal detachment. The ranges for the reported rates were similar for the XEN45 and trabeculectomy (0 to 2.2% vs 0 to 1.2%, respectively).

- Reintervention rates are generally moderate and similar for the XEN45 and trabeculectomy. The most common reinterventions are post-XEN45 trabeculectomy (1.1% vs 0.0%), the placement of a drainage implant (3.8% vs 1.8%) and the placement of a second or first XEN45 (3.8% vs 0.6%).
- Bleb needling rates following XEN45 implantation vary greatly from study to study (5.4% to 46.2%) and are predominantly higher for the XEN45.

Quality of life

- The identified studies report that at 6 and 15 months, the quality of life of patients who had undergone XEN45 implantation or trabeculectomy had not improved or deteriorated.

Expert perspective

- The experts consulted are of the opinion that the XEN45 can provide a clinical benefit to certain patients. Indeed, based on their experience with the device, the experts maintain that, to them, the XEN45's efficacy appears to be comparable or inferior (depending on the target IOP) to that of trabeculectomy, but that its safety and its impact on quality of life appear to be superior. For them, the XEN45 is an additional option that would address certain needs and gaps in current management.

Role of the XEN45 in the care continuum

- The role of the XEN45 in the POAG care continuum has not yet been clearly determined.
- The experts consulted identified certain types of patients who could particularly benefit from a less invasive surgical option than the current last-resort options. They estimate that approximately half of trabeculectomies could potentially be replaced with XEN45 implantations.
- The experts judged that the XEN45 could provide some other advantages over trabeculectomy, such as shorter and less complex surgeries.

Economic analyses

Efficiency analysis

At the price submitted by the manufacturer, XEN45 implantation is not considered efficient and would be associated with an incremental cost of approximately $[redacted] per eye relative to trabeculectomy when the interventions are performed alone, and over $[redacted] when performed in conjunction with phacoemulsification. It should be noted that there is still some uncertainty regarding the maintenance of the clinical benefits over the longer term.

Budget impact analysis

According to the base case scenario, access to public coverage for those devices for patients with moderate to advanced POAG may lead to additional expenses estimated at more than $[redacted] in the first 3 years.

SUMMARY OF DELIBERATIONS AND RECOMMENDATION

The members of the Comité d'excellence clinique en santé (CEC – santé) recognize the clinical utility of the XEN45. However, the cost-benefit ratio, about which there is some uncertainty, was considered too high. In the interest of fairness, the Committee's members consider that public coverage of the XEN45 could be a fair and reasonable option if an economic burden mitigation measure is put in place.

Reasons for the unanimous position

- The members recognized that the clinical data demonstrate the device's efficacy in reducing IOP and the pharmacotherapy required. However, they noted that the extent of the clinical gain appears to be similar to that provided by trabeculectomy. They also noted the level of evidence for the comparison, which is considered low.
- The clinical data indicate that the XEN45 has a safety profile similar to that of trabeculectomy. Although the members recognized the less invasive nature of XEN45 implantation, some of them are concerned about the associated bleb needling rates.
- The additional costs related to the device were considered high, and there is some uncertainty as to the maintenance of benefits in the long term.
- The members feel that the less complex surgery with the XEN45 could be performed by a greater number of specialists, which could result in better access to the procedure for patients in remote areas. The members reiterated the importance of addressing the access-to-care issues for the entire target population.
- The members consider that the XEN45 constitutes a relevant additional treatment option in the care continuum for primary open-angle glaucoma.

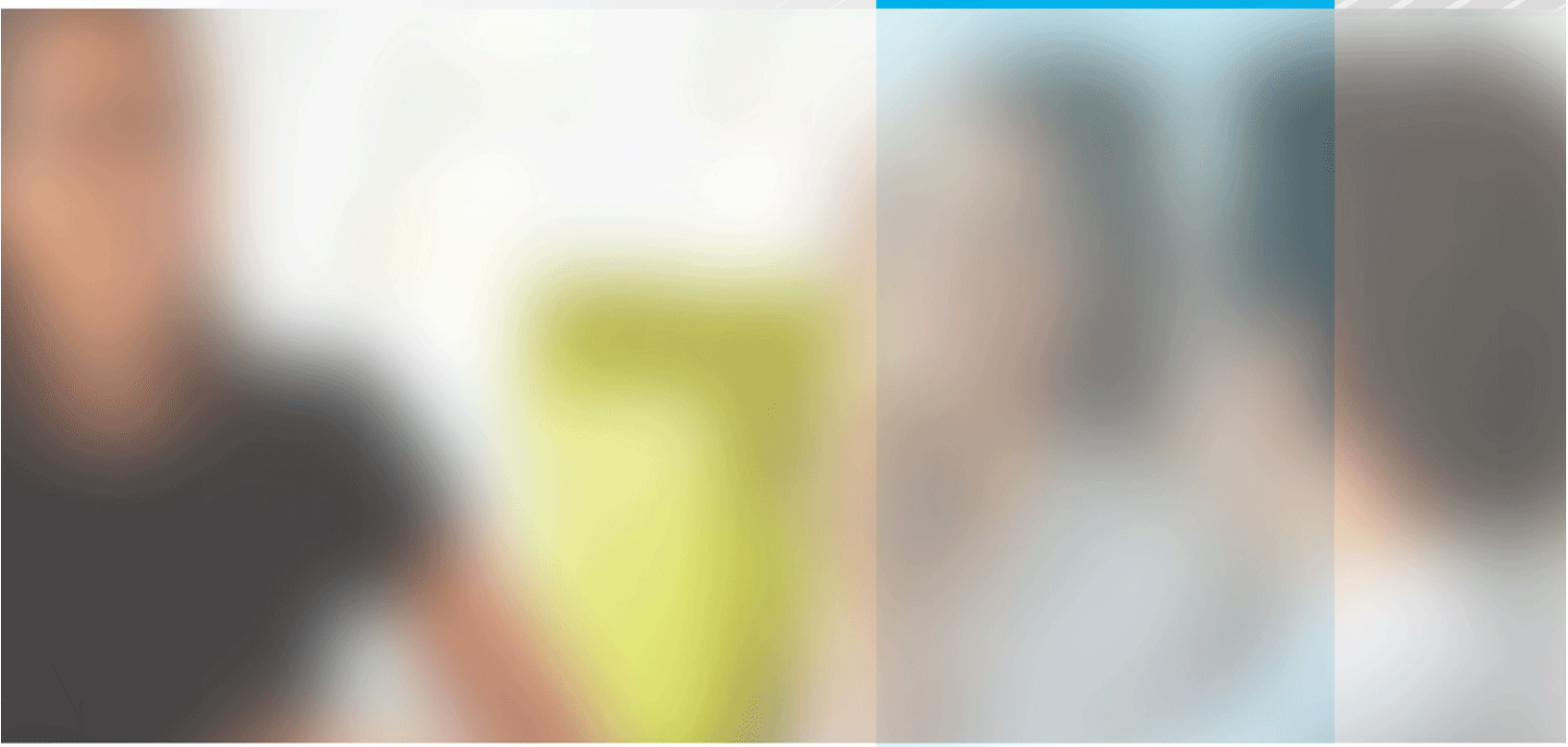
INESSS's recommendation

In light of the available information, the Institut national d'excellence en santé et en services sociaux (INESSS) is of the opinion that public coverage of the XEN45 gel implant could be a fair and reasonable decision if economic burden mitigation measures were put in place and their use governed by the following criteria:

- Patients with refractory glaucoma, despite maximum tolerated hypotonizing medication or with a documented medical condition preventing the optimal administration of the drops.

Other considerations

1. Given the longer-term uncertainties regarding its therapeutic value, the offer of service should be reassessed at a later date in light of the new data available. A 3-year time horizon is suggested.
2. Any broadening of the proposed criteria should be done only in the context of evidence development with financial support from the manufacturer.



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