



2019 Health Technology Reassessment Report

## Macular Translocation

## Summary

### □ **Background**

The Health Insurance Review & Assessment Services (HIRA) Benefit Assurance Preliminary Coverage Office sought the opinions of relevant academic societies (associations) on items on the no-coverage list before the introduction of the Innovative Health Technology Assessment system to determine whether or not to change their coverage status (to preliminary coverage). Subsequently, HIRA requested the Korea National Evidence-based Healthcare Collaborating Agency (NECA) to perform a health technology reassessment. "Macular Translocation," currently not covered by the national health insurance (classification ID Jo 664), is an invasive surgery performed for patients with age-related macular degeneration (AMD) and other eye diseases. It is performed to relocate the retina to a healthy choroid site that is not affected by neovascularization by removing subfoveal choroidal neovascularization (CNV) and translocating the macula. The surgery is mainly used to treat AMD, but several complications, including retinal detachment, can occur. Accordingly, its use is limited to AMD patients with no other treatment option according to the NICE guidelines.

### □ **Committee Operation**

During the NECA reassessment staff researcher meeting, it was determined that a subcommittee of 3 members recommended by the Korean Ophthalmological Society should be assembled. To assess macular translocation, the subcommittee determined the methods of assessment and establishing the research protocol, selecting articles, performing data synthesis, and deriving conclusions. The subcommittee held 3 meetings.

### □ **Purposes and Methods**

In this study, all methods of assessment (including the patients, the purpose of use, and the definition of the surgical procedure) were finalized during the 1st

subcommittee meeting based on the previous health technology assessments performed in and outside Korea, literature reviews, and ophthalmologist consultations. The PICO-TS (proposed) of the macular translocation assessment was as follows.

Categories	Details
Patients	<ul style="list-style-type: none"> <li>- Age-related macular degeneration (AMD)</li> <li>- Subfoveal choroidal neovascularization (CNV)</li> <li>- Pathologic myopia</li> <li>- Angioid streaks</li> <li>- Pathologic myopia</li> <li>- Punctate inner choroidopathy</li> <li>- Atrophic maculopathy</li> <li>- Degenerative myopia</li> <li>- Ocular histoplasmosis syndrome</li> </ul>

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Categories	Details
Intervention	<ul style="list-style-type: none"> <li>- Macular translocation               <ul style="list-style-type: none"> <li><input type="checkbox"/> Limited macular translocation (LMT, 180 degrees)</li> <li><input type="checkbox"/> Full macular translocation (FMT, 360 degrees)</li> </ul> </li> </ul>
Comparators	<ul style="list-style-type: none"> <li>- Photodynamic therapy (PDT)</li> <li>- Autologous RPE-choroid patch graft (PG)</li> <li>- Removal of choroidal neovascularization (CNV removal)</li> </ul>
Outcomes	<ul style="list-style-type: none"> <li>- Safety               <ul style="list-style-type: none"> <li><input type="checkbox"/> Complications</li> </ul> </li> <li>- Effectiveness               <ul style="list-style-type: none"> <li><input type="checkbox"/> Near and distance acuity (NVA)</li> <li><input type="checkbox"/> Contrast sensitivity (CS)</li> <li><input type="checkbox"/> Best-corrected visual acuity (BCVA)</li> <li><input type="checkbox"/> Recurrence of CNV</li> <li><input type="checkbox"/> Quality of life (VRQOL): MEO-VFQ 25 questionnaire</li> </ul> </li> </ul>
Timing	Not restricted

## □ Results

The safety assessment showed that macular translocation was associated with severe complications such as retinal detachment, macular pucker, and macular hole. In addition, mild complications, such as diplopia and macular edema, occurred. In contrast, there were fewer reports of complications after photodynamic therapy (PDT).

Regarding effectiveness, the report of the best-corrected visual acuities (BCVA; a critical outcome variable) after 12 and 24 months in the randomized controlled clinical trials reviewed in this study was graded as "low" quality evidence. The reports on the recurrence of CNV were graded as "very low" quality evidence, and those on the quality of life index were graded as "low" quality evidence. The reports on improvements in near visual acuity (NVA) and contrast sensitivity (CS), both important outcome variables, were also graded as "low" quality evidence.

To conclude, the evidence was insufficient to determine that macular translocation, a surgical procedure to remove subfoveal CNV and improve visual acuity in AMD and other eye diseases, is effective compared with PDT, as reported by previous studies.

## □ Conclusion

Based on the assessment results, the "Macular Translocation" subcommittee expressed the following opinions.

Macular translocation is a surgical procedure for removing subfoveal CNV and improving visual acuity in AMD and other eye diseases, as shown in previous studies. The evidence is insufficient to conclude that it is effective, compared with PDT.

However, as recommended by the NICE guideline, macular translocation can be limited to AMD patients who did not show improvement after intravitreal injection of anti-vascular endothelial growth factor (currently used as the first therapy for

AMD) and do not have any other treatment option. Thus, the subcommittee recommended that macular translocation should be performed by skilled physicians and the surgery should only be performed after patients consent to the surgery after an adequate provision of information on adverse events.

Based on the subcommittee's review, the Health Technology Reassessment Committee determined the following for "macular translocation" (November 8, 2019).

The Health Technology Reassessment Committee recommends the use of "macular translocation." But its use should be limited to AMD patients who have no other treatment option (Grade of recommendation: I-b. Strength of recommendation: Low).