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[C2H2112] Summary of Cost-effective Analysis Evaluation of Micra Transcatheter Pacing System (Micra AV)

1. Purpose of use

Leadless transcatheter pacemakers

2. Price of the device

Micra AV has been reimbursed since December 2021, and the device has been priced at JPY 1,170,000 as of March 2023. The price was determined using the Similar Efficacy Comparison Method with a 10% premium. The product wase designated as an item for the cost-effectiveness evaluation with H2 classification.

3. Scope of the cost-effectiveness evaluation

Micra AV is a dual-chamber transcatheter leadless pacemaker. The scope of the cost-effectiveness evaluation determined in the first session of the Expert Committee of Cost–Effectiveness Evaluation (ECCEE) is described below.

The target population was patients who have atrioventricular block, indicated for a pacemaker without atrial fibrillation, and who should be precluded from using a transvenous pacemaker to avoid complications.

The comparator is a DDD-mode transvenous pacemaker because it is exclusively used for the target population.

Target population	Patients who have an atrioventricular block indicated for a pacemaker without atrial fibrillation and who should be precluded from using a transvenous pacemaker
Comparator	DDD mode transvenous pacemaker

4. Evaluation of additional benefits

The manufacturer used data from studies on Micra VR and VVI leadless pacemakers because, as the manufacturer explained, the complication profiles of Micra VR and Micra AV are considered the same. In the Micra Transcatheter Pacing Study, complication rates were significantly lower for Micra VR (n=725) than for transvenous pacemakers, collected from historical control data (n=2,667) (HR:0.46 (95%CI:0.28 to 0.74)).

The manufacturer concluded that Micra AV had additional benefits.

In addition, several observational studies have showed that complication rates were lower in Micra (leadless pacemakers) than in transvenous pacemakers. Therefore, the academic group accepted the manufacturer's conclusions.

5. Results of the cost-effectiveness analysis

The manufacturer performed a cost-effectiveness analysis using a Markov model. Utility values until six months after implantation were generated by mapping the aggregated SF-36 scores reported in a previous study to those of the EQ-5D using the algorithm developed in another study. The utility values 12 months after implantation was estimated from the simple assumption that the difference in utility values between Micra AV and the comparator after 12 months was one-fourth of that until six months. Hospitalization costs were estimated from the claims data analysis.

In the academic analysis, utility values up to six months were derived from data on SF-36 scores from another study in which the results were matched with covariates. No additional benefit in terms of utility was observed after 12 months. Hospitalization costs were estimated using the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB) for larger samples, excluding those with primary diseases that were not indications for pacemakers. The ECCEE accepted the following:

Population	Comparator	ICER (JPY/QALY)
Patients who have an atrioventricular block indicated for a pacemaker without atrial fibrillation and who should be precluded from using a transvenous pacemaker	DDD mode transvenous pacemaker	14,073,538