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[C2H2302] Summary of cost-effectiveness evaluation of the aortic stent graft (The GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System)

1. Purpose of use

- Thoracic aortic aneurysms
- Complicated Stanford type B aortic dissection (including dissecting aortic aneurysms) in patients who did not respond to medical treatment
- Traumatic aortic transaction

2. Price of the device

The GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System (the Gore CTAG stent graft with ACS) has been reimbursed since July 2023 at JPY 1,490,000 (as of October 2024). The price was determined using a Similar Efficacy Comparison Method, with a 5% premium. The product was designated as an item for cost-effectiveness evaluation using the H2 classification.

3. Scope of cost-effectiveness evaluation

This product is indicated for treating patients with thoracic aortic aneurysms (TAA), complicated Stanford type B aortic dissections (including dissecting aortic aneurysms) that do not respond to medical treatment (TBAD), and traumatic aortic transactions. The scope of evaluation agreed upon during the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE), is described below.

Population	(a) Thoracic aortic aneurysms (b) Complicated Stanford type B aortic dissection (including dissecting aortic aneurysm) who do not respond to medical treatment
Comparator	Conventional aortic stent-grafts

4. Evaluation of additional benefits

The manufacturer selected the outcomes as the number of stent grafts initially implanted, overall survival, reintervention incidence, and deployment with rapid ventricular pacing and conducted a systematic review. Although two studies of the Gore CTAG stent graft with ACS were identified, including the SURPASS registry, no studies have focused on directly comparing efficacy and safety with conventional aortic stent grafts. Therefore, indirect comparisons were conducted to evaluate additional benefits. For patients with TAA, although the Gore CTAG stent graft with ACS was associated with fewer initial device uses and deployment with rapid ventricular pacing, there was no significant difference in overall survival and re-intervention incidence compared with conventional aortic stent grafts. For patients with TBAD, although the Gore CTAG stent graft with ACS was associated with a lower incidence of reintervention and fewer deployments with rapid ventricular pacing, there was no significant difference in initial device use and overall survival compared with conventional aortic stent grafts. Of the four outcomes set by the manufacturer, the Academic Technology Assessment Group (ATAG) considered overall survival and reintervention incidence to be the appropriate outcomes and independently conducted a systematic review. The ATAG reanalysis found that indirect comparisons were challenging to perform due to the SURPASS registry's failure to report results relevant to the target population and the lack of sufficient data. However, the data suggests that the addition of ACS to conventional stent graft may be effective in reducing the number of initial device implantations and deployments with rapid ventricular pacing, although it is not clear how these outcomes would affect the clinical outcomes. Based on these results, the ATAG was unable to determine whether the Gore CTAG stent graft with ACS had additional benefits over the conventional aortic stent graft.

5. Results of the cost-effectiveness analysis

The manufacturer conducted a cost-effectiveness analysis using a Markov model with four health states: initial surgery, postoperative follow-up, re-intervention, and death. The analysis model assumed that the quality-of-life scores did not vary by health status in either analysis group, resulting in a cost-minimization analysis. For both the assessment and comparator technology, the manufacturer used reintervention data for TAA from the GREAT registry, which evaluated previous-generation stent grafts. For TBAD, they used re-intervention data from the GREAT registry as the assessment technology and the MOTHER registry, which evaluated other manufacturers' products, as the comparator technology. ATAG found no additional benefit for either TAA or TBAD and performed a cost-minimization analysis. The ATAG conducted a reanalysis of TAA and TBAD using reintervention incidence data from the GREAT registry for both assessment and comparator technology. The ECCEE accepted the following results.

Population	Comparator	Additional benefit(s)	ICER (JPY/QALY)
(a) Thoracic aortic aneurysms	Conventional aortic stent-grafts	Not proven	Cost saving
(b) Complicated Stanford type B aortic dissection (including dissecting aortic aneurysm) who do not respond to medical treatment	Conventional aortic stent-grafts	Not proven	Cost saving