



July 20th, 2023

[C2H2115] Summary of Cost-effectiveness Analysis Evaluation of Expedium Verse Fenestrated Screw System

1. Purpose of use

Spine fixation

2. Price of the device

Expedium Verse Fenestrated Screw (EVFS) system has been reimbursed since March 2022, and the device is priced at JPY 101,000 per screw as of April 2023. The price was determined using the Similar Efficacy Comparison Method with a 5% premium. The product was designated as an item for the cost-effectiveness evaluation with H2 classification.

3. Scope of Cost-effectiveness Evaluation

The EVFS is a fenestrated spine fixation screw used for spinal fusion. The scope of the cost-effectiveness evaluation determined at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below.

The target population was osteoporotic patients with reduced bone strength who undergo multi-intervertebral spinal fusion using spinal fixation screws. The comparator was a non-fenestrated spine fixation screw with artificial bone.

Target population	Osteoporotic patients with reduced bone strength who undergo multi-intervertebral spinal fusion using spinal fixation screw
Comparator	Non-fenestrated spine fixation screw + artificial bone (Target technology: Expedium Verse Fenestrated Screw + bone cement)

4. Evaluation of additional benefits

In a previous systematic review and meta-analysis, revision rates after spinal fusion in osteoporotic patients were significantly lower for fenestrated screws (1.33 (95% CI:0.56%-2.09%)) than for non-fenestrated screws (4.85% (95% CI:2.31%-7.39%)) ((p=0.009)).

Based on these results, the manufacturer concluded that the EVFS system had additional benefits.

However, the comparators in the previous study were not limited to non-fenestrated screws with artificial bones. As other studies show that using artificial bone improves spine fixation, it is not appropriate to regard this study as evidence that matches the scope.

Although the academic group conducted systematic reviews to identify observational studies and single-arm clinical trials, and considered the possibility of indirect comparisons, it was not possible to identify evidence that matched the scope.

Therefore, the academic group concluded that the target technology could not be judged as having an additional benefit.

5. Results of the cost-effectiveness analysis

The manufacturer conducted a cost-minimization analysis regardless of the additional benefit that the manufacturer claimed, as a cost reduction was expected during its analysis. The analysis included medical device and adverse effect costs, assuming that other costs, such as administration costs, did not differ between the groups.

In the academic analysis, since the medical device price of non-fenestrated screw, part of the comparator had been revised from JPY 93,500 to JPY 79,100, it used the renewed price.

The ECCEE accepted the following criteria:

Population	Comparator	ICER (JPY/QALY)
Osteoporotic Patients with reduced bone strength who undergo multi-intervertebral spinal fusion using spinal fixation screw	Non-fenestrated spine fixation screw + artificial bone	Cost increase