



2023年4月13日

[C2H2104] Summary of cost-effectiveness evaluation of daratumumab and vorhyaluronidase alfa (DARZQURO®)

1. Indications

- Multiple myeloma
- Systemic AL amyloidosis

2. Price of the drug

Daratumumab and vorhyaluronidase alfa (DARZQURO®) has been reimbursed from May 2021 at JPY 445064 (as of January 2022). The price is calculated using a similar efficacy comparison method, with a 5% usefulness premium (II). This product is designated as the H1 item for cost-effectiveness evaluation.

3. Scope of cost-effectiveness evaluation

This product is intended for treating multiple myeloma or systemic AL amyloidosis. The evaluation scope, which was agreed upon during the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE), is described below.

Population	<u>Multiple myeloma</u> Newly diagnosed multiple myeloma (NDMM) ineligible for hematopoietic stem cell transplantation and relapsed or refractory multiple myeloma (RRMM) <u>Systemic AL amyloidosis</u> Newly diagnosed AL amyloidosis
Comparator	<u>Multiple myeloma</u> Intravenous daratumumab (DARA IV) (Selected technology: Subcutaneous Daratumumab (DARA SC))

	<p><u>Systemic AL amyloidosis</u></p> <p>Cyclophosphamide, bortezomib, and dexamethasone (CyBorD) (Selected technology: Daratumumab plus bortezomib, cyclophosphamide, and dexamethasone (DCyBorD))</p>
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4. Evaluation of additional benefits

[NDMM and RRMM] As a result of the systematic review, the randomized COLUMBA trial was detected, which compared the DARA SC with the DARA IV. The trial results indicated that DARA SC demonstrated no additional benefit over DARA IV in terms of ORR, PFS, and OS. Thus, the academic group concluded that DARA SC has “no additional benefits” over DARA IV.

[Systemic AL amyloidosis] The randomized ANDROMEDA trial was detected in the systematic review, which compared DCyBorD with CyBorD. In this trial, CR was higher in the DCyBorD group than in the CyBorD group (OR:5.1,95% CI:3.2 to 8.2, $p < 0.001$). Furthermore, MOD-PFS was significantly longer in the DCyBorD group than in the CyBorD group. However, OS data were still premature during the primary analysis. Consequently, the academic group concluded that DCyBorD has additional benefits for the comparator.

5. Results of the cost-effectiveness analysis

The manufacturer performed a cost-minimization analysis for the NDMM and RRMM. For systemic AL amyloidosis, the manufacturer developed a cost-utility analysis model consisting of a decision tree paired with a Markov model.

In the NDMM and RRMM analyses, the academic group estimated the hospitalization period for patients treated with DARA SC or IV based on the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB). In the case of systemic AL amyloidosis, the manufacturer’s analysis was acceptable, and the academic group renewed the drug price.

Population	Comparator	ICER (JPY/QALY)
Newly diagnosed multiple myeloma (NDMM) ineligible for hematopoietic stem cell transplantation and relapsed or refractory multiple myeloma (RRMM)	DARA IV	Cost-saving
Newly diagnosed AL amyloidosis	CyBorD	5,645,767