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[C2H2303] Ritlecitinib (Litfulo Capsule)

1. Purpose of use

Alopecia areata (where the area of hair loss is extensive and intractable)

2. Price of the drug

Ritlecitinib has been reimbursed since August 2023, with a drug price of JPY 5,802 for Litfulo Capsule 50 mg as of January 2025. The price was determined using the Similar Efficacy Comparison Method, incorporating a 5% usefulness premium (II) and a 5% pediatric premium. The product was designated as an item for cost-effectiveness evaluation under the H1 classification.

3. Scope of Cost-effectiveness Evaluation

This product is indicated for the treatment of severe alopecia areata. The scope of evaluation, as agreed upon during the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below:

Target population	(a)	Adult alopecia areata patients with more than 50% of hair loss area
	(b)	Pediatric alopecia areata patients with more than 50% of hair loss area (age of 12 years or older)
Comparator	(a)	Baricitinib
	(b)	Best supportive care (BSC)

4. Evaluation of additional benefits

Population (a): Adult population

A systematic review (SR) conducted by the academic group did not identify any randomized controlled trials (RCTs) directly comparing ritlecitinib and baricitinib.

Therefore, the additional benefit was evaluated using a network meta-analysis, with the placebo groups from the ALLEGRO-2b/3 and BRAVE-AA1/AA2 trials serving as common control treatments. The analysis yielded an odds ratio of 1.27 (95% CI: 0.10 to 16.75) for achieving a SALT score of 20 or less at 24 weeks with ritlecitinib compared to baricitinib. While the point estimate exceeded 1, the wide range of the 95%CI made it difficult to clearly interpret the superiority of efficacy between the two drugs. Therefore, the academic group concluded that ritlecitinib does not demonstrate an additional benefit over baricitinib.

Population (b): Pediatric population

The SR conducted by the academic group identified the ALLEGRO-2b/3 trial as the only RCT comparing ritlecitinib with placebo. The academic group used subgroup results from this trial to evaluate additional benefits.

In the subgroup analysis, 25% of patients receiving ritlecitinib achieved a SALT score of 20 or less at 24 weeks, compared to 0% in the placebo group. While the trial did not perform statistical testing for the subgroup owing to its insufficient sample size, the manufacturer noted that these results were consistent with those observed in the overall population (ritlecitinib: 23%, placebo: 2%) and argued that an additional benefit was demonstrated for the pediatric population. The academic group considered the manufacturer's evaluation of the additional benefit as acceptable and concluded that ritlecitinib provided an additional benefit over best supportive care (BSC).

5. Results of the cost-effectiveness analysis

The manufacturer conducted a cost-minimization analysis for population (a) and a cost-utility analysis for population (b) using a cohort Markov model. This model comprised eight health states, defined by the presence or absence of active treatment (ritlecitinib or baricitinib), SALT scores, and one death state.

The academic group revised the following parameters: ages and SALT scores achieved through active treatment for the population (b); and the proportion of deaths within 48 weeks for both population groups. Also, in the manufacturer's analysis for population (b), the comparator group continued BSC despite the availability of baricitinib after the patients turned 15 years old. The academic group argued that baricitinib should be considered as the next-line treatment in the comparator group. However, the ECCEE accepted the scenario analysis presented by the academic group, in which the comparator group continued with BSC for a lifetime. The results of the analysis are as follows:

Population	Comparator	ICER (JPY/QALY)
(a) Adult alopecia areata patients with more than 50% of hair loss area	Baricitinib	Cost increase
(b) Pediatric alopecia areata patients with more than 50% of hair loss area	BSC	7,129,443