A Cost-per-Responder Analysis of Ritlecitinib and Baricitinib: Assessing the Impact of Clinical Efficacy and Dosing Variability on Overall Treatment Costs of Severe Alopecia Areata

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INTRODUCTION

- Alopecia areata (AA) is an autoimmune disease characterized by patchy or complete nonscarring hair loss on the scalp, with or without additional loss of facial and/or body hair[1]
- Ritlecitinib, a Janus kinase 3 (JAK3) and tyrosine kinase expressed in hepatocellular carcinoma (TEC) family kinase inhibitor, is approved for the treatment of both adults and adolescents aged 12 years and older with severe AA.[2] Baricitinib, a JAK1/2 inhibitor, is approved for the treatment of adults (aged ≥18 years) with severe AA[3]
- Ritlecitinib 50 mg daily demonstrated efficacy in the ALLEGRO phase 2b/3 study (NCT03732807) at 24 and 48 weeks[4]
- The BRAVE-AA1/-AA2 trials (NCT03570749; NCT03899259) demonstrated that baricitinib 2 mg and 4 mg were superior to placebo in achieving scalp hair regrowth; however, a higher dose response was observed with baricitinib 4 mg compared with baricitinib 2 mg at 36 and 52 weeks[5,6]
- Despite the improved efficacy of the baricitinib 4 mg dose over the 2 mg dose, payer coverage policies may require initiation of the 2 mg dose given its lower comparative cost. This may lead to patients receiving less effective treatment, potentially necessitating subsequent up-titration and ultimately resulting in a delay in care
- Ritlecitinib is currently available as a single dose of 50 mg daily at a lower cost than baricitinib 4 mg daily, offering a straightforward dosing strategy and potential cost savings

OBJECTIVE

- This study aimed to develop a cost-per-responder (CPR) analysis for ritlecitinib 50 mg, and baricitinib 2 mg and 4 mg for the treatment of severe AA to estimate the budget impact of these new therapies resulting from differences in clinical efficacy, available dosages, and pricing structure

METHODS

- A decision tree was developed to evaluate the cost implications of once-daily ritlecitinib 50 mg, or baricitinib 2 mg and 4 mg treatment across a 1-year time horizon from a US perspective
  - Drug costs were estimated using wholesale acquisition costs[7] (**Table 1**)
  - Distribution across initial treatment and dosing options was based on real-world evidence (RWE)[8]
- Shorter-term treatment response was defined as Severity of Alopecia Tool (SALT) score relative change from baseline of ≥30% (SALT Δ ≥30%) at Weeks 18 and 24, and longer-term treatment response as absolute SALT score of ≤20 at Weeks 36 and 52
- The shorter-term and longer-term time points were dependent on the data reported in the clinical trials for each treatment[4,5]
- Patients initiating baricitinib 2 mg who did not have shorter-term treatment response were allowed to up-titrate to 4 mg or discontinue therapy
  - All baricitinib 2 mg patients who up-titrated to baricitinib 4 mg were assumed to up-titrate at Week 18 based on RWE[8]
  - The proportion of patients responding to baricitinib at the interim time points was estimated based on the proportion of patients with early or gradual response in King et al (2023)[9]
- Shorter-term non-responders who did not up-titrate and longer-term non-responders were considered to have discontinued therapy
- Decision probabilities were derived from RWE and clinical trial data[8,9]
- This analysis modeled pathways for populations aligned with the patient ages per the US prescribing information[2]
- Scenario analyses were conducted to assess the CPR of ritlecitinib 50 mg, and baricitinib 2 mg and 4 mg in 3 scenarios:
  - Baricitinib 2 mg only (all baricitinib patients received 2 mg)
  - Baricitinib 4 mg only (all baricitinib patients received 4 mg)
  - Cost equivalence at Week 52*

*The point when the percentage of patients initiating baricitinib 2 mg would result in the total baricitinib costs being equal to the total ritlecitinib costs.

Table 1. Drug cost inputs[7]

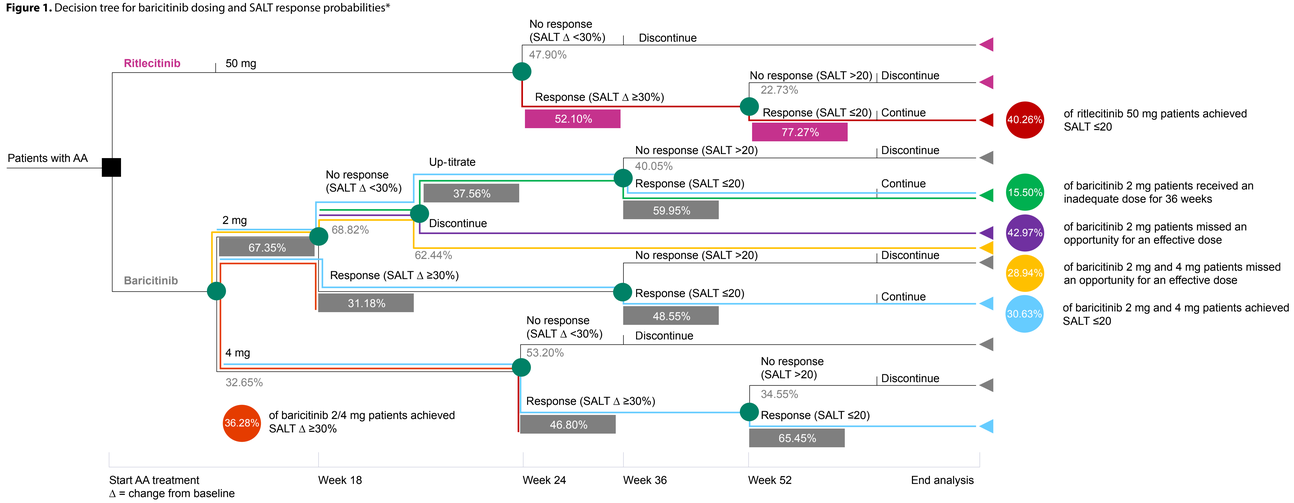
Drug	National Drug Code	Units/ package	Package price, $	Cost/ unit, $
Ritlecitinib 50 mg	00069-0334-28	28	3957.69	141.35
Baricitinib 2 mg	00002-4182-30	30	2739.99	91.33
Baricitinib 4 mg	00002-4479-30	30	5479.98	182.67

RESULTS

Base case results

- At Week 24, **52.10% of ritlecitinib 50 mg initiators** and **36.28% of baricitinib 2/4 mg initiators** achieved SALT Δ ≥30% (**Figure 1**)
- At Week 52, **40.26% of ritlecitinib 50 mg initiators** and **30.63% of baricitinib 2/4 mg initiators**, achieved SALT ≤20
- Baricitinib 2/4 mg had a higher CPR than ritlecitinib 50 mg at Weeks 24 ($54,887 vs $45,577) and 52 ($107,217 vs $94,834) (**Table 2**)
- **42.97% of baricitinib 2 mg patients** missed an opportunity for an effective dose (i.e. patients on baricitinib 2 mg who discontinued after no response to baricitinib 2 mg); **28.94% of baricitinib 2 mg and 4 mg patients** missed an opportunity for an effective dose (i.e. patients on baricitinib 2 mg or 4 mg who discontinued after no response to baricitinib 2 mg)
- **15.50% of baricitinib 2 mg patients** received an inadequate dose for 36 weeks (i.e. patients who responded to baricitinib 4 mg following up-titration after previously not responding to baricitinib 2 mg)

Figure 1. Decision tree for baricitinib dosing and SALT response probabilities*



AA, alopecia areata; SALT, severity of alopecia tool.
*The proportion of patients with response was calculated by multiplying probabilities along the same branch and adding probabilities along different branches. For example, the proportion of baricitinib 2/4 mg initiators who achieved SALT Δ ≥30% was calculated as follows: (32.65% x 46.80%) + (67.35% x 31.18%) = 36.28%.

Table 2. Base case results

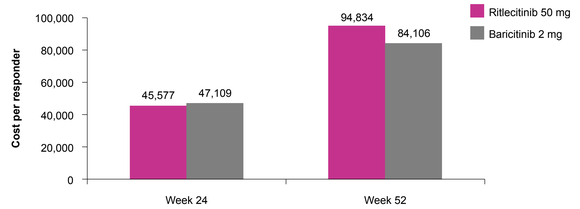
	Ritlecitinib 50 mg	Baricitinib 2/4 mg*	Absolute difference
Total drug costs, $			
At Week 24	23,746	19,911	3835
At Week 52	38,180	32,841	5339
Responders, %†			
At Week 24‡	52.10	36.28	15.82
At Week 52‡	40.26	30.63	9.63
Cost per responder, $			
At Week 24	45,577	54,887	9310
At Week 52	94,834	107,217	12383

*Represents the composite of all patients receiving baricitinib (2 mg and 4 mg). †Shorter-term treatment response was defined as Severity of Alopecia Tool (SALT) score relative change from baseline ≥30% (SALT Δ ≥30%) at Weeks 18 and 24, and longer-term treatment response as absolute SALT score ≤20 at Weeks 36 and 52. ‡The proportion of patients with response was calculated by multiplying probabilities along the same decision tree branch and adding probabilities along different branches. For example, the proportion of baricitinib 2/4 mg initiators who achieved SALT Δ ≥30% was calculated as follows: (32.65% x 46.80%) + (67.35% x 31.18%) = 36.28%.

Scenario analysis results

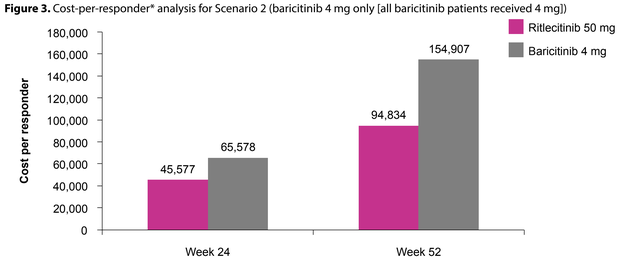
- Baricitinib 2 mg only (all baricitinib patients received 2 mg)
  - Ritlecitinib 50 mg CPR was lower than that for only baricitinib 2 mg at Week 24 (difference: −$1532) and higher at Week 52 (difference: $10,728) (**Figure 2**)
- Baricitinib 4 mg only (all baricitinib patients received 4 mg)
  - Ritlecitinib 50 mg CPR was lower than that for only baricitinib 4 mg at Weeks 24 and 52 (difference: −$20,001 and −$60,073, respectively) (**Figure 3**)
- Cost equivalence at Week 52
  - Cost equivalence was reached at Week 52 at $38,180 with 42.72% of baricitinib patients initiating 2 mg treatment
  - Ritlecitinib 50 mg CPR was $94,834 and baricitinib 2/4 mg CPR was $124,655 for total drug cost equivalence at 52 weeks (**Figure 4**)

Figure 2. Cost-per-responder* analysis for Scenario 1 (baricitinib 2 mg only [all baricitinib patients received 2 mg])



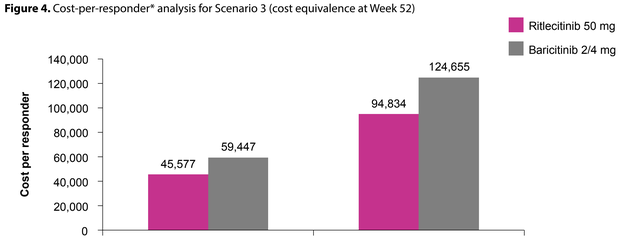
SALT, Severity of Alopecia Tool.
*Shorter-term treatment response was defined as SALT score relative change from baseline ≥30% at Weeks 18 and 24, and longer-term treatment response as absolute SALT score ≤20 at Weeks 36 and 52.

Figure 3. Cost-per-responder* analysis for Scenario 2 (baricitinib 4 mg only [all baricitinib patients received 4 mg])



SALT, Severity of Alopecia Tool.
*Shorter-term treatment response was defined as SALT score relative change from baseline ≥30% at Weeks 18 and 24, and longer-term treatment response as absolute SALT score ≤20 at Weeks 36 and 52

Figure 4. Cost-per-responder* analysis for Scenario 3 (cost equivalence at Week 52)



SALT, Severity of Alopecia Tool.
*Shorter-term treatment response was defined as SALT score relative change from baseline ≥30% at Weeks 18 and 24, and longer-term treatment response as absolute SALT score ≤20 at Weeks 36 and 52

LIMITATIONS

- Given the modeling approach, the results may be sensitive to response assessment timepoints and up-titration timing, which may vary in clinical practice
- The model only accounts for drug acquisition costs, which do not include additional costs, such as costs from laboratory tests, adverse events, or healthcare encounters associated with the treatment
- The response values were based on naive comparisons, and head-to-head data between ritlecitinib and baricitinib are not available
- Real-world adherence was not fully accounted for due to lack of published analyses; however, discontinuations due to a lack of response were captured through the model assumptions
- Given the lower efficacy of baricitinib 2 mg,[10] clinicians are unlikely to recommend the use of only the 2 mg dose, thereby limiting the real-world applicability of Scenario 1

CONCLUSIONS

- Ritlecitinib 50 mg demonstrates a lower CPR than baricitinib 2/4 mg at Weeks 24 and 52, which was supported by the scenario analyses
  - Although the total cost for ritlecitinib 50 mg was higher than that for baricitinib 2/4 mg, the CPR was lower because ritlecitinib had greater efficacy for more patients at an earlier stage and fewer discontinuations than in patients who started on baricitinib 2 mg
  - Starting patients on a lower effective dose (baricitinib 2 mg) may lead to discontinuation in patients who may have responded to ritlecitinib 50 mg or baricitinib 4 mg
- An indirect treatment comparison found ritlecitinib 50 mg to have similar efficacy to baricitinib 4 mg.[10] The current analysis supports a lower CPR with ritlecitinib 50 mg compared with baricitinib 4 mg
- These findings support reimbursement or formulary inclusion of ritlecitinib for the treatment of AA

Presented at ISPOR 2025; May 13-16, 2025; Montreal, QC, Canada

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DISCLOSURES

H Tran, AS Cha-Silva, SK Kurosky, and EH Law are employees of Pfizer Inc and own stock/stock options. KH Zhang and C Graham are employees of RTI Health Solutions. EJ Song reports relationships with BMS, AbbVie, Galderma, Alphyn, Acelyrin, Eli Lilly, Janssen, Novartis, UCB, Pfizer, Amgen, Dermavant, Arcutis, Incyte, SUN, Boehringer Ingelheim, Sanofi & Regeneron, and Ortho-dermatologics. This study was sponsored by Pfizer Inc. Medical writing and editorial support was provided by Nucleus Global, an Inizio company, which was funded by Pfizer Inc.

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