EE325

Budget Impact of Baricitinib for Patients with Severe Alopecia Areata

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BACKGROUND

- Alopecia areata (AA) is an autoimmune disorder characterized by nonscarring hair loss [1]. Clinical presentation ranges from small, well-defined patches of hair loss to a complete loss of hair on the body and scalp [1].
- Approximately 0.21% of the US population has AA [1]. Severe AA, defined as >50% score on the Severity of Alopecia Tool (SALT), is experienced by 0.04-0.09% of individuals in the US, resulting in as many as 300,000 US patients overall [1].
- Studies have linked AA with autoimmune involvement driven by infiltration of CD4+ and CD8+ T cells into immune privilege (IP) sites of the hair follicles (HFs), which results in loss of the growing hair shaft and IP collapse [3].
- Corticosteroids, minoxidil, and immunomodulators are used to treat AA [4]. However, there are no FDA-approved therapies and current off-label treatments provide limited benefit in this population [2].
- Janus kinase (JAK) inhibitors are promising upcoming treatments for AA because they block the promotion of HF IP collapse [5]. JAK inhibitors have already demonstrated efficacy across several inflammatory diseases, such as psoriasis, rheumatoid arthritis (RA), and atopic dermatitis [2].
- Baricitinib is an oral JAK inhibitor that is approved for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more tumor necrosis factor antagonist therapies and is under FDA review for approval for the treatment of adult patients with severe AA.

OBJECTIVE

- The objective of this study was to estimate the budget impact of baricitinib for the treatment of patients with severe AA from a US third-party payer perspective, as well as to understand key model drivers.

KEY RESULTS

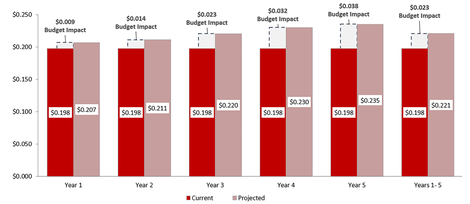
Base Case

- With projected baricitinib market shares of 0.7%, 1.1%, 1.8%, 2.6%, and 3.0% in years 1-5, respectively, a total of 4, 6, 10, 14, and 17 patients receive baricitinib in the projected scenario in each year.
- The budget impact of baricitinib is $0.009 per member per month (PMPM) in year 1, with the incremental cost increasing each year as baricitinib market uptake increases for a budget impact of $0.038 in year 5, leading to an overall budget impact of $0.023 PMPM in years 1-5 (**Figure 1**).
- The total budget in the baseline scenario was $11,851,216 and the total budget in the projected scenario was $13,234,561, leading to an incremental budget impact of $1,383,345. This budget impact was driven by an increase in treatment costs of $1,361,179. Baricitinib was also associated with a moderate increase in monitoring costs ($22,166) (**Table 4**).

Table 4. Base case results (Years 1-5)

Model Result	Without Baricitinib	With Baricitinib	Absolute Change	Relative Change
Total eligible patients	555	555	0	NA
Treatment costs	$11,405,817	$12,766,996	$1,361,179	11.93%
Monitoring costs	$445,399	$467,565	$22,166	4.98%
Total budget	**$11,851,216**	**$13,234,561**	**$1,383,345**	**11.67%**
PMPM	**$0.198**	**$0.221**	**$0.023**	**11.67%**

Figure 1. PMPM budget impact by year over 5-year period



OWSA

- 72 parameters were included in the one-way sensitivity analysis (OWSA), including inputs for market adoption, epidemiology, treatment monitoring, and treatment administration. These parameters were varied by ±20% of their base case value iteratively.
- Budget impact results were most sensitive to epidemiological inputs including the percentage of adults (target population), AA prevalence, percentage of severe AA, and percentage of severe AA on treatment. In addition, the results were sensitive to the projected market shares for baricitinib across the 5-year time horizon. However, results remained robust relative to the base case budget impact of $0.023 PMPM with a maximum range of variation of $0.018 PMPM to $0.028 PMPM.
- When excluding epidemiology inputs from the OWSA, the model was most sensitive to the projected baricitinib market shares for years 1-5, baricitinib monitoring costs, and the unit cost for office visits; however, PMPM values remained within $0.002 of the base case.
- Tornado diagrams of the base case OWSA, with and without epidemiology inputs, are presented in **Figures 2-3.**

Figure 2. Tornado diagram of one-way sensitivity analysis including epidemiology inputs

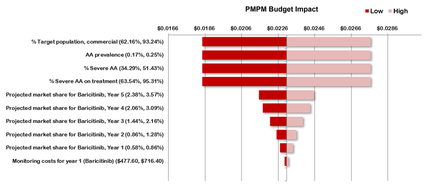
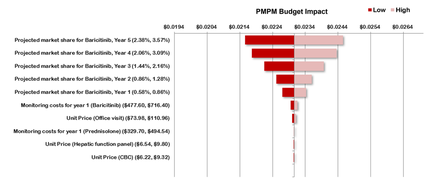


Figure 3. Tornado diagram of one-way sensitivity analysis excluding epidemiology inputs



LIMITATIONS

- There are currently no FDA-approved treatments for AA. Therefore, the model includes off-label treatments used in clinical practice, which aligns with the NAAF treatment algorithm, ACE consensus statements, and real-world treatment patterns from a Lilly real-world study [8-10].
- The baseline market share data uses Lilly real-world treatment patterns data [10]. To apply these data, the model assumes that class-level market shares are divided evenly across individual treatments within each class. Additionally, the total real-world utilization exceeds 100% in the Lilly real-world study as some patients received more than one treatment. Therefore, to ensure that the baseline market shares for all comparators in the model sum to 100%, the model assumes that the utilization of topical corticosteroids, which have the highest market share, is 100% minus the sum of all other treatment classes.
- The base case estimates do not include drug rebates, dispensing fees, or cost-sharing.
- Topical contact immunotherapy (DPCP, SADBE, and DNCP) are included in the NAAF treatment algorithm [8]; however, these therapies were excluded from the model. Topical contact immunotherapy is compounded in a pharmacy or clinic and therefore do not have assigned codes to properly identify these treatments in claims data. It would be challenging to accurately assign market share and treatment costs to this drug class, as there are no manufacturers of topical contact immunotherapy.

CONCLUSIONS

- Under the base case scenario with a commercial plan of one million covered lives, the PMPM budget impact of baricitinib is small ($0.023). This budget impact corresponds with a 0.7%, 1.1%, 1.8%, 2.6%, and 3.0% uptake of baricitinib in years 1-5 respectively.
- The OWSA results revealed that the PMPM budget impact was most sensitive to inputs that affect the eligible population size. When removing epidemiology parameters from the OWSA, results were most sensitive to baricitinib market uptake over the five-year time horizon.
- The addition of baricitinib to a formulary is expected to have a small impact on a plan's budget when considering a market basket that reflects real-world treatment patterns. OWSA results demonstrated that the budget impact was generally robust across 20% variation in the population with severe AA. Population size and baricitinib market uptake in the projected scenario were most likely to affect results.

METHODS

Model Structure

- An Excel-based model was constructed using a comparative cost determination framework to evaluate the net budget impact of treating patients with severe AA under an existing formulary (baseline scenario), compared to a scenario in which baricitinib is available (projected scenario).
- The analysis was conducted from a US commercial payer perspective with a five-year time horizon.
- All costs are reported in 2021 US dollars.

Target Population

- Using a top-down epidemiology cascade, the model estimates the number of treatment-eligible patients with severe AA.
- The model starts with a hypothetical population of one million covered lives and applies a series of epidemiological estimates to quantify the target population eligible for baricitinib.
- **Table 1** shows the detailed population estimates for patients with severe AA starting with the adult US population (age ≥18 years) [6].
- Next, the model estimates the number of diagnosed patients with severe AA by applying overall AA prevalence and the percentage of AA cases that are severe, both derived from the literature [1].
- Finally, the number of patients with severe AA on treatment is estimated using data from a National Alopecia Areata Foundation (NAAF) survey [7].
- The total population eligible for baricitinib is calculated as the number of patients with severe AA on treatment. The same calculation is applied to estimate the eligible annual cohort entering the model each year.

Table 1. Population and epidemiology inputs

	Input (%)	Population Size				
		Year 1	Year 2	Year 3	Year 4	Year 5
Covered Lives*	--	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000
Adults 18+[6]	77.70	777,000	777,000	777,000	777,000	777,000
AA prevalence[1]	0.21	1,632	1,632	1,632	1,632	1,632
Percentage of severe AA^[1]	42.86	699	699	699	699	699
Percentage of severe AA on treatment[7]	79.43	555	555	555	555	555
Total eligible population		**555**	**555**	**555**	**555**	**555**

*Assumption
^ Severe AA is defined as >50% score on the Severity of Alopecia Tool [2]

Comparators

- The list of treatments for severe AA is based on reconciliation of real-world treatment patterns data, the Alopecia Areata Consensus of Experts (ACE) consensus statements, and the NAAF treatment algorithm [8-10].
- The base case market basket includes the following comparators:
  - Topical corticosteroids (0.25% desoximetasone, 0.05% clobetasol propionate)
  - Intralesional corticosteroids (triamcinolone acetonide)
  - Topical non-steroids (minoxidil 5%)
  - Systemic corticosteroids (prednisone, prednisolone)
  - Immunomodulators
    - JAK inhibitors in addition to baricitinib (tofacitinib, ruxolitinib)
    - Methotrexate, cyclosporine, and azathioprine

Market Basket Inputs

- The baseline market shares were obtained from a Lilly real-world AA treatment patterns study [10]. The model assumes equal shares across all treatments within a class (**Table 2**).
- Projected market shares for baricitinib were obtained from Lilly market forecast data (**Table 2**). Equi-proportional adoption of baricitinib across comparators is assumed in the base case.

Table 2. Baseline and projected market shares for severe AA

Population	Baseline Market Shares (%)*	Projected Market Shares (%)^				
	Years 1-5	Year 1	Year 2	Year 3	Year 4	Year 5
Baricitinib	0.0	0.7	1.1	1.8	2.6	3.0
Topical corticosteroids						
0.25% desoximetasone	30.4	30.1	30.0	29.8	29.6	29.4
0.05% clobetasol propionate	30.4	30.1	30.0	29.8	29.6	29.4
Intralesional corticosteroids						
Triamcinolone acetonide	0.1	0.1	0.1	0.1	0.1	0.1
Topical non-steroids						
Minoxidil 5%	5.6	5.6	5.5	5.5	5.5	5.4
Systemic corticosteroids						
Prednisone	15.0	14.9	14.8	14.7	14.6	14.6
Prednisolone	15.0	14.9	14.8	14.7	14.6	14.6
Immunomodulators						
Tofacitinib	0.7	0.7	0.7	0.7	0.7	0.7
Ruxolitinib	0.7	0.7	0.7	0.7	0.7	0.7
Methotrexate	0.7	0.7	0.7	0.7	0.7	0.7
Cyclosporine	0.7	0.7	0.7	0.7	0.7	0.7
Azathioprine	0.7	0.7	0.7	0.7	0.7	0.7
Total	**100**	**100**	**100**	**100**	**100**	**100**

*Baseline market shares were sourced from a real-world treatment patterns study [10]
^Projected baricitinib uptake was obtained from Lilly market forecast data [11], and an equi-proportional pull was assumed to calculate the projected market shares for all comparators

Cost Inputs

- The default dosing assumptions for each comparator were based on product prescribing information (PI).
- Unit costs were derived for each treatment option based on 2021 wholesale acquisition cost (WAC) data from Medi-span Price Rx [12]. In the base case analysis, cost-sharing, rebates, and dispensing fees were all assumed to be zero. The calculated annual treatment costs account for the dosing requirements for each drug (**Table 3**). A 12-month treatment duration was assumed for all comparators to ensure comparability of results in the base case.
- Subcutaneous (SC) injections of triamcinolone acetonide were assumed to be self-administered and have no associated administration costs. Baricitinib and remaining comparators are either oral or topical medications and were assumed to have no administration costs.
- Monitoring requirements for each treatment were based on the product PIs. Costs for each monitoring resource were based on national payment rates from the Centers for Medicare and Medicaid Services (CMS) physician fee schedule and the CMS laboratory fee schedule [13-14]. Per the product PIs, monitoring costs were divided into two time periods: prior to treatment and during treatment. Given the default treatment duration is 12 months, total monitoring costs were applied for the first year for each cohort (**Table 3**).

Table 3. Annual treatment and monitoring costs

Comparator	Annual Treatment Cost^	Annual Monitoring Cost (Year 1)
Baricitinib	$30,919.20	$597.00
Topical corticosteroids		
0.25% desoximetasone	$432.00	$109.18
0.05% clobetasol propionate	$600.00	$109.18
Intralesional corticosteroids		
Triamcinolone acetonide	$67.65	$179.01
Topical non-steroids		
Minoxidil 5%*	$0.00	$0.00
Systemic corticosteroids		
Prednisone	$358.18	$0.00
Prednisolone	$12,013.83	$412.12
Immunomodulators		
Tofacitinib	$64,096.37	$597.00
Ruxolitinib	$191,802.00	$597.00
Methotrexate	$222.48	$1,447.50
Cyclosporine	$12,536.64	$114.44
Azathioprine	$506.25	$1,704.08

*Minoxidil is an over-the-counter medication and therefore it incurs no cost to the payer in the base case model
^Treatment costs are calculated using 2021 WAC unit costs [12]

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DISCLOSURES

- **IQVIA Disclosures:** This study was sponsored by Eli Lilly and Company. Katherine Rosettie, Tianyi Lu*, and Cheryl Ferrufino are employees of IQVIA, which received funding from Eli Lilly and Company for conducting this study and developing this poster
- **Eli Lilly and Company Disclosures:** Christian Fenske, Mark Borns*, Nate Johnson, and Paula Morrow are employees and shareholders of Eli Lilly and Company

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