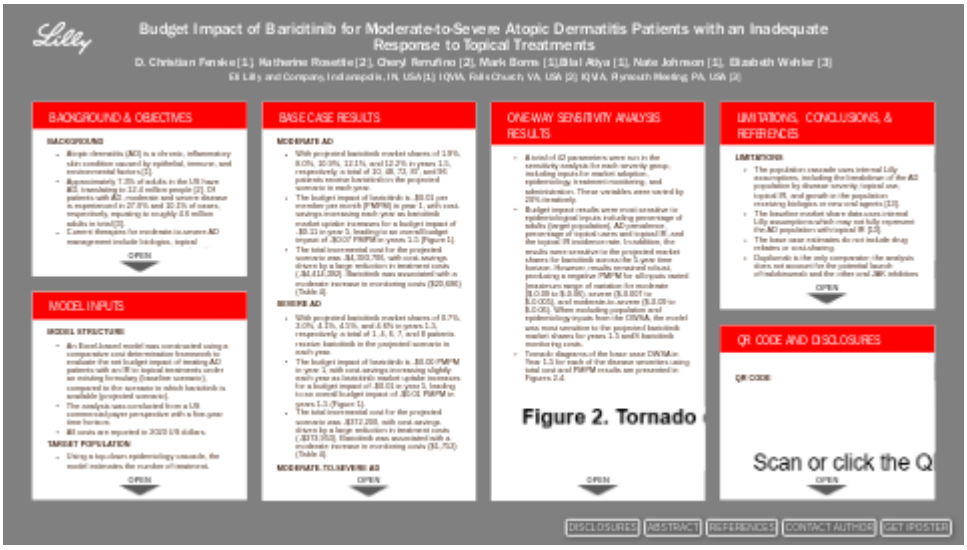
Budget Impact of Baricitinib for Moderate-to-Severe Atopic Dermatitis Patients with an Inadequate Response to Topical Treatments



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BACKGROUND & OBJECTIVES

BACKGROUND

- Atopic dermatitis (AD) is a chronic, inflammatory skin condition caused by epithelial, immune, and environmental factors [1].
- Approximately 7.3% of adults in the US have AD, translating to 12.4 million people [2]. Of patients with AD, moderate and severe disease is experienced in 27.0% and 10.1% of cases, respectively, equating to roughly 4.6 million adults in total [3].
- Current therapies for moderate-to-severe AD management include biologics, topical treatments, immunosuppressants, phototherapy, and/or systemic steroids [4-6]. While most patients can achieve symptom improvement or control, patients do experience treatment failure, which may include inadequate clinical improvement, failure to achieve long-term control, decrease in quality of life, and/or experience of adverse events [4].
- FDA-approved systemic therapy for management of moderate-to-severe AD in patients with inadequate response (IR) to topical treatments has been limited to dupilumab [7].
- Dupilumab offers a novel therapeutic approach; however, it may not be suitable for all patients with AD due to the subcutaneous (SC) administration along with the differing immunophenotypes present in AD [8-9]. Therefore more treatment options, particularly oral medications, are needed [10-11].
- Baricitinib is an oral Janus kinase (JAK) inhibitor that is currently 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 currently under review by the Food and Drug Administration (FDA) for the treatment of adult patients with moderate-to-severe AD.

OBJECTIVES

- The objective of this study was to estimate the budget impact of baricitinib for the treatment of patients with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies from a US third-party payer perspective, as well as to understand key model drivers.

MODEL INPUTS

MODEL STRUCTURE

- An Excel-based model was constructed using a comparative cost determination framework to evaluate the net budget impact of treating AD patients with an IR to topical treatments under an existing formulary (baseline scenario), compared to the 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 2020 US dollars.

TARGET POPULATION

- Using a top-down epidemiology cascade, the model estimates the number of treatment-eligible patients by disease severity (moderate, severe, and moderate-to-severe).
- The model starts with a hypothetical population of 1 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 moderate, severe and the combined moderate-to-severe AD patients starting with the adult US population (age ≥18 years) [12]. Estimates of prevalence, incidence, and proportion of patients on topical therapy are applied.
- Incident moderate-to-severe AD topical IR are assumed to be drawn from the population of initially mild/clear AD cases that become moderate or severe AD cases over time. The total number of incident moderate-to-severe AD topical IR for each year is added to the prevalent moderate-to-severe AD topical IR, leading to growth in the IR population over time.
- The population is subsequently filtered down to topical IR who are receiving biologic or new oral agents [13]. The model accounts for growth in the population eligible for biologic or new oral agents using Lilly market utilization data [13]. The model assumes 100% of moderate-to-severe topical users with IR who are receiving biologics or new oral agents are eligible for baricitinib.

Table 1. Population and epidemiology inputs

	Input (%)	Population Size				
		Year 1	Year 2	Year 3	Year 4	Year 5
Adults 18+[12]	77.64	776,400	776,400	776,400	776,400	776,400
AD prevalence[2]	7.3	56,677	56,677	56,677	56,677	56,677
Total topical users[13]	86	48,742	48,742	48,742	48,742	48,742
Percentage of topical users with:[13^]						
Moderate AD	41.3	20,131	20,131	20,131	20,131	20,131
Severe AD	9.6	4,679	4,679	4,679	4,679	4,679
Moderate to Severe AD	50.9	24,810	24,810	24,810	24,810	24,810
Incident AD topical inadequate responders[13^]						
Moderate AD	6.85	3,340	3,340	3,340	3,340	3,340
Severe AD	1.59	776	776	776	776	776
Moderate to Severe AD	8.45	4,116	4,116	4,116	4,116	4,116
Inadequate responders[13^]						
Moderate AD	60.3	15,479	15,479	15,479	15,479	15,479
Severe AD	57.7	3,476	3,476	3,476	3,476	3,476
Moderate to Severe AD	59.81	18,955	18,955	18,955	18,955	18,955
Percentage receiving biologic or new oral agents[13]	3.48	--	--	--	--	--
Annual growth of biologic or new oral agents[13^]	0.4	--	--	--	--	--
Total eligible population*						
Moderate AD		539	600	662	723	785
Severe AD		121	135	149	162	176
Moderate to Severe AD		660	735	810	886	961

*Assumption
^ The 5-point Physician Global Assessment (PGA) scale was used to define disease severity, where a score of 3 was defined as moderate AD and a score of 4 was defined as severe AD. Moderate to severe AD was defined as the population with PGA scores of 3 or 4 [18].

COMPARATORS

- The base case market basket includes dupilumab, which is the only systemic therapy currently indicated for moderate-to-severe AD with topical IR.

MARKET BASKET

- Given that dupilumab was the only treatment in the baseline market basket, it was assigned 100% of the market share across the 5-year time horizon.
- Projected market shares for baricitinib were obtained from Lilly market forecast data. The projected baricitinib uptake varied by disease severity, with the highest projected baricitinib uptake in the moderate AD population

(Table 2).

Table 2. Projected baricitinib uptake by disease severity					
Population	**Baricitinib Uptake (%)**				
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Moderate AD	1.9	8.0	10.9	12.1	12.2
Severe AD	0.7	3.0	4.1	4.5	4.6
Moderate to Severe AD	1.7	7.0	9.5	10.6	10.7

COST INPUTS

- The default dosing assumptions for each comparator were based on product prescribing information (PI).
- Unit costs of drug acquisition were derived for each treatment option based on 2020 wholesale acquisition cost (WAC) data from Medi-span Price Rx [14]. 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). We assume a five-year treatment duration for all comparators.
- Subcutaneous (SC) injections of dupilumab were assumed to be self-administered and have no associated administration costs. Baricitinib is an oral medication and was assumed to have no administration costs.
- Monitoring requirements for each treatment were based on the product PIs. The model does not incorporate any routine monitoring for dupilumab in accordance with the dupilumab PI [15]. Costs for each monitoring resource were based on national payment rates per the Centers for Medicare and Medicaid Services (CMS) physician fee schedule and the CMS laboratory fee schedule [16-17]. Total monitoring costs were calculated by year; for patients receiving therapy for more than 12 months, monitoring resource use and costs are assumed to be the same as those in the 6-12 month time frame. The model assumed higher monitoring resource use in the first year of therapy and therefore the annual monitoring costs were higher in the first year compared to subsequent years (Table 3).

Table 3. Annual treatment and monitoring costs			
Comparator	**Annual Treatment Cost***	**Annual Monitoring Cost (Year 1)**	**Annual Monitoring Cost (Year 2+)**
Baricitinib	$29,445.00	$134	$64
Dupilumab**	$43,541.40	$0	$0

*Treatment costs are calculated using WAC 2020 unit costs.
**Dupilumab is slightly more expensive in year 1 than in subsequent years due to a higher induction dose.

BASE CASE RESULTS

MODERATE AD

- With projected baricitinib market shares of 1.9%, 8.0%, 10.9%, 12.1%, and 12.2% in years 1-5, respectively, a total of 10, 48, 72, 87, and 96 patients receive baricitinib in the projected scenario in each year.
- The budget impact of baricitinib is -$0.01 per member per month (PMPM) in year 1, with cost-savings increasing each year as baricitinib market uptake increases for a budget impact of -$0.11 in year 5, leading to an overall budget impact of -$0.07 PMPM in years 1-5 (Figure 1).
- The total incremental cost for the projected scenario was -$4,393,706, with cost-savings driven by a large reduction in treatment costs (-$4,414,392). Baricitinib was associated with a moderate increase in monitoring costs ($20,686) (Table 4).

SEVERE AD

- With projected baricitinib market shares of 0.7%, 3.0%, 4.1%, 4.5%, and 4.6% in years 1-5, respectively, a total of 1, 4, 6, 7, and 8 patients receive baricitinib in the projected scenario in each year.
- The budget impact of baricitinib is -$0.00 PMPM in year 1, with cost-savings increasing slightly each year as baricitinib market uptake increases for a budget impact of -$0.01 in year 5, leading to an overall budget impact of -$0.01 PMPM in years 1-5 (Figure 1).
- The total incremental cost for the projected scenario was -$372,200, with cost-savings driven by a large reduction in treatment costs (-$373,953). Baricitinib was associated with a moderate increase in monitoring costs ($1,752) (Table 4).

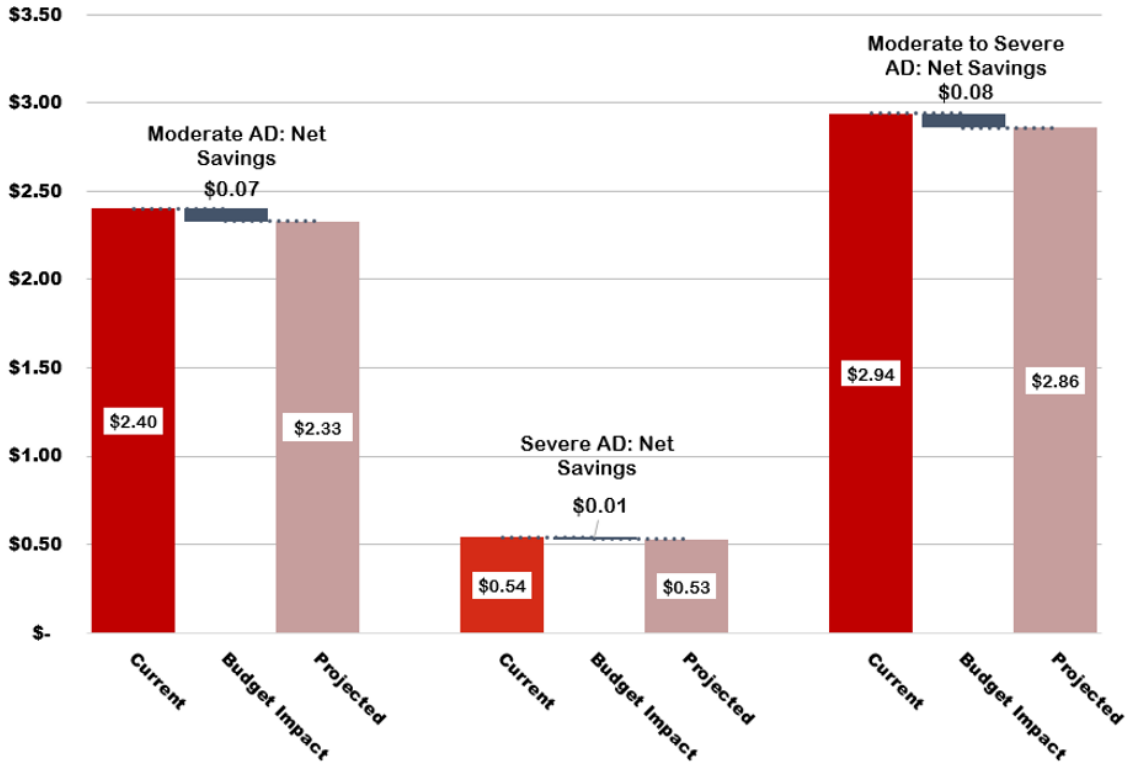
MODERATE-TO-SEVERE AD

- With projected baricitinib market shares of 1.7%, 7.0%, 9.5%, 10.6%, and 10.7% in years 1-5, respectively, a total of 11, 52, 77, 94, and 103 patients receive baricitinib in the projected scenario in each year.
- The budget impact of baricitinib is -$0.01 PMPM in year 1, with cost-savings increasing each year as baricitinib market uptake increases for a budget impact of -$0.12 in year 5, leading to an overall budget impact of -$0.08 PMPM in years 1-5 (Figure 1).
- The total incremental cost for the projected scenario was -$4,719,710, with cost-savings driven by a large reduction in treatment costs (-$4,741,931). Baricitinib was associated with a moderate increase in monitoring costs ($22,221) (Table 4).

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

Model Result	Without Baricitinib	With Baricitinib	Absolute Change	Relative Change
Moderate AD				
Overall cost to plan	$144,077,843	$139,684,137	-$4,393,706	-3.05%
Treatment costs	$144,077,843	$139,663,451	-$4,414,392	-3.06%
Monitoring costs	$0	$20,686	$20,686	NA
PMPM	**$2.40**	**$2.33**	**-$0.07**	**-3.05%**
Severe AD				
Overall cost to plan	$32,357,818	$31,985,617	-$372,200	-1.15%
Treatment costs	$32,357,818	$31,983,865	-$373,953	-1.16%
Monitoring costs	$0	$1,752	$1,752	NA
PMPM	**$0.54**	**$0.53**	**-$0.01**	**-1.15%**
Moderate to severe AD				
Overall cost to plan	$176,435,661	$171,715,951	-$4,719,710	-2.68%
Treatment costs	$176,435,661	$171,693,730	-$4,741,931	-2.69%
Monitoring costs	$0	$22,221	$22,221	NA
PMPM	**$2.94**	**$2.86**	**-$0.08**	**-2.68%**

Figure 1. PMPM budget impact over 5-year period



ONE-WAY SENSITIVITY ANALYSIS RESULTS

- A total of 42 parameters were run in the sensitivity analysis for each severity group, including inputs for market adoption, epidemiology, treatment monitoring, and administration. These variables were varied by 20% iteratively.
- Budget impact results were most sensitive to epidemiological inputs including percentage of adults (target population), AD prevalence, percentage of topical users and topical IR, and the topical IR incidence rate. In addition, the results were sensitive to the projected market shares for baricitinib across the 5-year time horizon. However, results remained robust, producing a negative PMPM for all inputs varied (maximum range of variation for moderate ($-0.09 to $-0.06), severe ($-0.007 to $-0.005), and moderate-to-severe ($-0.09 to $-0.06). When excluding population and epidemiology inputs from the OWSA, the model was most sensitive to the projected baricitinib market shares for years 1-5 andS baricitinib monitoring costs.
- Tornado diagrams of the base case OWSA in Year 1-5 for each of the disease severities using total cost and PMPM results are presented in Figures 2-4.

Figure 2. Tornado diagram of one-way sensitivity analysis for moderate AD

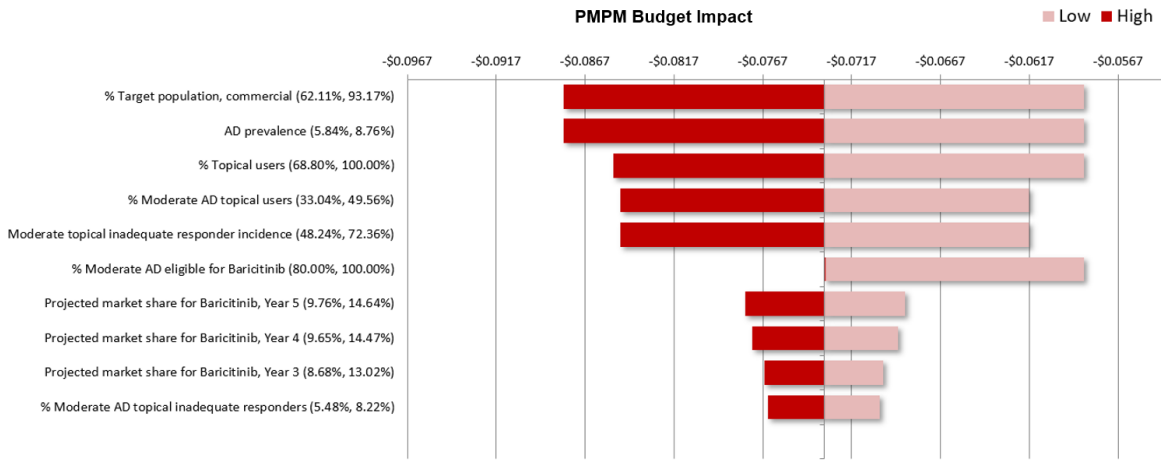


Figure 3. Tornado diagram of one-way sensitivity analysis for severe AD

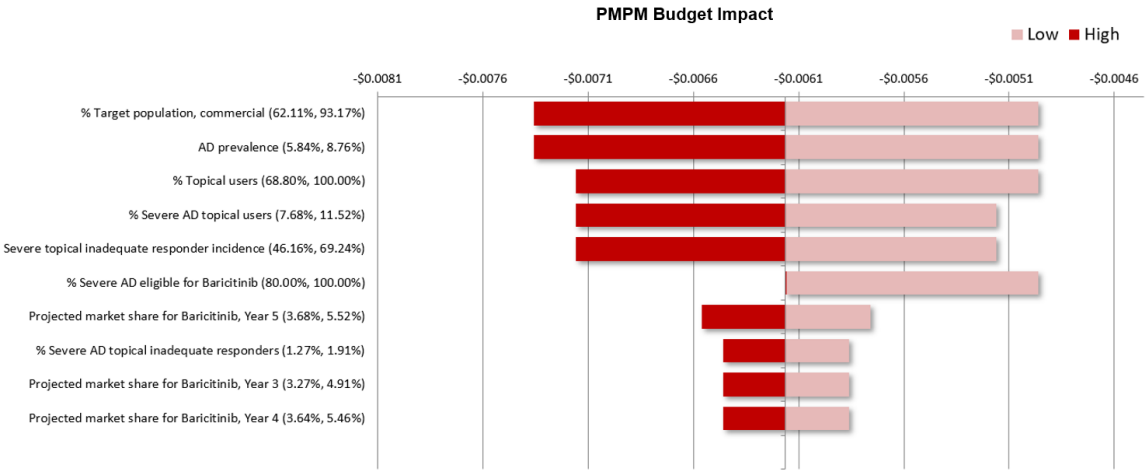
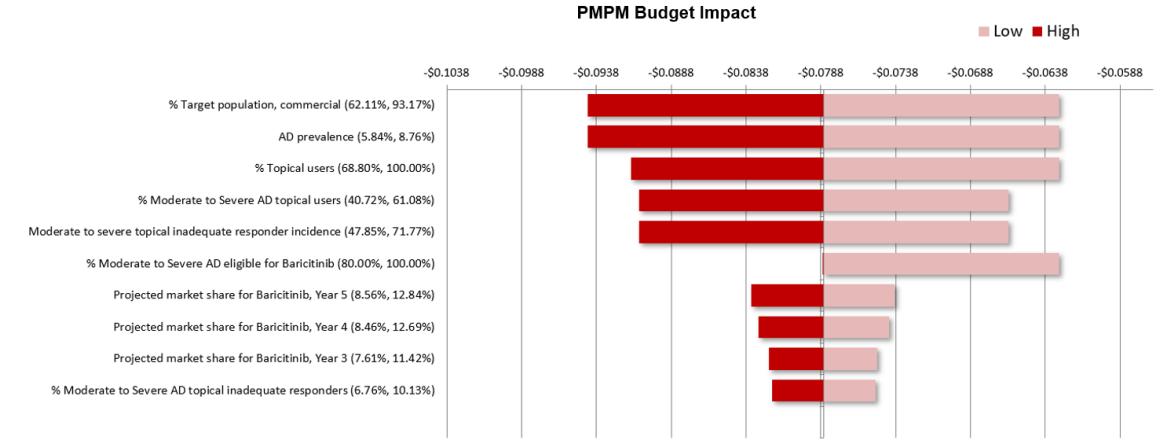


Figure 4. Tornado diagram of one-way sensitivity analysis for moderate-to-severe AD



LIMITATIONS, CONCLUSIONS, & REFERENCES

LIMITATIONS

- The population cascade uses internal Lilly assumptions, including the breakdown of the AD population by disease severity, topical use, topical IR, and growth in the population receiving biologics or new oral agents [13].
- The baseline market share data uses internal Lilly assumptions which may not fully represent the AD population with topical IR [13].
- The base case estimates do not include drug rebates or cost-sharing.
- Dupilumab is the only comparator; the analysis does not account for the potential launch of tralokinumab and the other oral JAK inhibitors over the five-year time horizon.

CONCLUSIONS

- With baricitinib uptake expected to be the highest among those with moderate AD, the relative PMPM budget impact is associated with the largest cost-savings in this population (-3.05%), yet cost-savings are estimated across all three disease severities.
- Even accounting for the modest market uptake in the severe AD population, the budget impact remains cost-saving at -$0.01 PMPM across the 1-5 year period.
- The OWSA results revealed that the results were most sensitive to epidemiology inputs that affect the eligible population size.
- The addition of baricitinib to a formulary budget would result in a cost-saving budget impact across all three disease severities, with the greatest relative cost-savings in the moderate AD population where baricitinib market uptake is expected to be the highest. Given the robustness of the model results in sensitivity analyses, baricitinib is expected to be a cost-saving addition to a plan’s budget based on its lower annual cost compared to dupilumab.

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ABSTRACT

OBJECTIVES: Systemic therapy for management of moderate-to-severe atopic dermatitis (AD) in patients with inadequate response (IR) to topical treatments has been limited to dupilumab. Given the expected launch of baricitinib, an oral Janus kinase inhibitor indicated for this population, the budget impact of adding baricitinib to a commercial managed-care formulary for treatment of moderate-to-severe AD was estimated from a US payer perspective.

METHODS: A budget impact analysis was done using a comparative cost determination framework and a 5-year time horizon. Starting with a hypothetical commercial plan of one million lives, the model estimated the number of baricitinib-eligible patients by disease severity using AD prevalence, topical use, and IR to topical treatments. Baricitinib was assumed to draw market share from dupilumab, with uptake ranging from 2% to 12%, 1% to 5%, and 2% to 11% in the moderate, severe, and moderate-to-severe AD populations, respectively. Treatment costs excluded rebates and cost-sharing and were from published wholesale acquisition costs. Dosing, administration, and monitoring requirements were from product prescribing information. Unit costs were from publicly available fee schedules. One-way sensitivity analyses (OWSA) were performed by varying all parameters by 20%.

RESULTS: The net budget impact over 5-years in the moderate AD population was -$4,393,706 (-3.05%) with a -$0.07 per member per month (PMPM). In the severe AD population, the net budget impact was -$372,200 (-1.15%) with a PMPM of -$0.01. In the moderate-to-severe AD population, the net budget impact was -$4,719,710 (-2.68%) with a PMPM of -$0.08. OWSA results were consistent with the base case, with results most sensitive to changes in epidemiological inputs, baricitinib market shares, and monitoring costs.

CONCLUSIONS: Adding baricitinib to a formulary would result in cost-savings across all three disease severities, with the greatest relative cost-savings in the moderate AD population, given the lower annual cost compared to dupilumab.

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