

Topical Treatment Utilization for Patients With Atopic Dermatitis in the United States and Budget Impact Analysis of Crisaborole Ointment, 2%

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BACKGROUND

- Atopic dermatitis (AD) is a chronic inflammatory skin disease affecting between 6-13% of the population in the United States (US).¹
- AD is often treated with prescription topical corticosteroids (TCS) and topical calcineurin inhibitors (TCI).
 - Concerns regarding local cutaneous atrophy, striae formation, and systemic side effects limit broader use of TCS.^{2,4}
 - TCI are associated with application-site reactions and carry boxed warning for risk of malignancy (eg, skin and lymphoma).^{3,6}
- Crisaborole ointment is a nonsteroidal PDE4 inhibitor for the treatment of mild to moderate AD.
 - Clinical studies have demonstrated that crisaborole is effective⁷ and has a relatively low incidence of treatment-related treatment-emergent adverse events in patients with mild to moderate AD.⁸ Application site pain (mainly reported as burning or stinging) was the only treatment-related adverse event that occurred in 1% of patients (crisaborole: 4.4%; vehicle: 1.2%).⁷

OBJECTIVES

- The objectives of this study were:
 - To evaluate recent real-world treatment utilization and costs for TCS and TCI in the US.
 - To estimate the pharmacy budget impact of crisaborole ointment, 2% over a 2-year period in patients ≥2 years of age with AD, from a third-party US payer perspective.

METHODS

Real-world treatment utilization and costs (RWTUC)

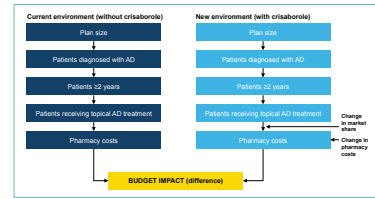
- The analysis assessed annual treatment patterns and associated costs of prescription topical therapies in patients who had a diagnosis of AD in 2015, using the Commercial and Medicare Supplemental claims from the Truven Health Analytics MarketScan[®] Research Databases from 1/1/2015 through 12/31/2015.
- All prescription utilization of TCS and TCI was assessed, and patients were classified by strategy based on how many different treatment categories they filled during 2015.
 - To capture the use of combination therapy by AD patients comprised of TCI and distinct categories of TCS potency, 9 mutually exclusive treatment strategies were defined:
 - TCS I-II only (representing high potency TCS)
 - TCS III-IV only (representing medium potency TCS)
 - TCS V-VII only (representing low potency TCS)
 - TCS I-VII (any multiple excluding above)
 - TCI only
 - TCI + TCS I-II only
 - TCI + TCS III-IV only
 - TCI + TCS V-VII only
 - TCI + TCS I-VII (any multiple excluding above)
- Each strategy with a TCS included at least one of the TCS strengths referred to in the group, but did not represent the order of the treatments received. The patient may have used more than one type generic drug within the same strength category.

- Patients with continuous enrollment for the entire calendar year 2015 were included if they had 1 or more diagnosis for AD (ICD-9 = 691.8 or ICD-10 = L20.1) at any time during 2015. Patients <2 years of age at time of diagnosis, having invalid medication quantity (METQTY <1 or >10 X tube size), or having invalid days' supply (DAYSSUP <1) were excluded.
- MarketScan data for TCS/TCI pricing represents the amount eligible for payment under the plan terms after applying rules such as discounts, but before applying copayments and deductible. In the absence of pharmacy claims for crisaborole, wholesale acquisition cost (WAC) is used in the BIM.

Crisaborole Budget impact model (BIM)

- Model structure
 - The incremental pharmacy budget impact due to changes in market share is calculated as the difference in costs between an environment reflecting the current shares of topical AD treatments without crisaborole, and an environment with projected shares including crisaborole.
 - The number of patients on each treatment in each scenario (ie, "current environment" and "new environment") and year is determined based on the size of the target population and market shares. The model then calculates the total costs based on annual per treatment per patient costs and number of patients on each treatment (Figure 1).
- Model inputs
 - Diagnosis and treatment rates, current market share, number of prescriptions per year, and payment (cost) per prescription were based on the real-world utilization analysis (see Results section).
 - The percentages of patients who are 2 years and older (97.53%) were based on US census data.⁹
 - Crisaborole uptake rates of 4.7% from TCS and 20.2% from TCI, with an annual increase of 1% in year 2, were assumed, based on a published BIM for a TCI.¹⁰
 - In the absence of current crisaborole utilization data, average number of prescriptions per patient from TCS I-II only, TCS III-IV only, TCS V-VII only, and TCI only groups was taken from the RWTUC analysis (1.46 prescriptions per year per patient). Cost per crisaborole prescription is \$580.00 based on WAC (one 60 gram tube of crisaborole per prescription).¹¹

Figure 1. Budget Impact Diagram



- Key AD – atopic dermatitis.
- Model outputs
 - The results are presented over 2 years in terms of total pharmacy budget and pharmacy cost per-member per-month (PMPM) without discounting.
 - Two AD populations were evaluated separately: patients receiving TCI or TCS alone or in combination ("TCS/TCI population") and patients receiving TCI alone or in combination with TCS ("TCI population"; excludes TCS alone).

RESULTS

Real-world treatment utilization and costs

- More than 70% of the population was 18-64 years old; patients in the 2-11 age group have the highest AD diagnosis rate (2.4%) (Table 1).
- Among all diagnosed patients, 50%-65% received TCS and/or TCI treatment, while only 2%-7% received TCI treatment with or without TCS (Table 1).
 - Based on these results, for a health plan with 1 million members, the target population size for the BIM was estimated as 4,706 when the TCS/TCI population was considered and 414 when the TCI population was considered.
- In the TCI/TCS population, the majority of the patients received medium potency TCS only (40.54%), while TCI population mostly used TCI alone (25%) or TCI combined with medium potency TCS (22.09%) (Table 2).
- The annual number of prescriptions per patient ranged from 1.36 to 6.41, with an annual cost per patient range of \$53.11-\$1,465.03 (Table 2, Figure 2).
 - Patients receiving TCS had similar annual number of prescriptions (1.36-1.49 for patients receiving TCS without TCI; 2.99-3.74 for patients receiving TCS with TCI), with a decreasing trend towards low potency TCS.
 - TCIs were associated with higher per-prescription costs (~\$470), and medium-potency TCS were less costly (~\$50), while low and high-potency TCS had similar costs (~\$180).
 - Patients using multiple types of TCS potencies in a year had the highest number of prescriptions and overall costs.

Crisaborole BIM

- For the TCI/TCS population, 285 and 332 patients were estimated to receive crisaborole in years 1 and 2, respectively (Figure 3).
 - The total budget impact of crisaborole over 2 years in the TCS/TCI population was \$350,946 (PMPM = \$0.015), with a total budget increase of \$162,106 in year 1 (PMPM = \$0.014) and \$188,841 in year 2 (PMPM = \$0.016).
- For the TCI population, 84 and 88 patients were estimated to receive crisaborole in years 1 and 2, respectively (Figure 3).
 - The total budget impact of crisaborole in the TCI population was a savings of \$27,871, with a total budget decrease of \$11,160 in year 1 (PMPM = -\$0.001) and \$11,712 in year 2 (PMPM = -\$0.001) (Figure 3).
- For both populations, budget impact was most sensitive to changes in crisaborole cost and annual usage in one-way sensitivity analyses.

KEY LIMITATIONS

- Costs associated with medical resources besides topical AD medications were excluded since data supporting differential non-medication resource use with crisaborole does not currently exist. Additionally, preliminary analysis of claims data indicated that the medical visit frequencies (except those for outpatient visits) are similar in patients with and without AD.
- As crisaborole is assumed to replace existing topical AD prescription treatments and is not expected to grow the number of patients treated for AD, patients untreated with prescription therapy by default do not receive crisaborole.
- The model does not exclude any patients based on disease severity given that the data source to populate the model (MarketScan claims data) does not differentiate patients by disease severity.
- If there is crisaborole uptake, it replaces all topical AD prescriptions in a year. Note: This analysis does not imply comparable efficacy, safety, or product interchangeability. No head-to-head clinical studies have been conducted to assess the efficacy or safety of crisaborole vs any TCS, TCI or any other prescription medications.

CONCLUSIONS

- Current utilization of topical prescription medications for AD have a material impact on pharmacy budget regardless of treatment choice.
 - Annual per-patient costs vary widely depending on the mechanism of action (TCI vs TCS) and TCS strength.
- Adoption of crisaborole results in a modest pharmacy budget impact or savings from the perspective of a US payer.

RESULTS (continued)

Table 1. Patient Demographics, and Diagnosis and Treatment Rates from RWTUC Analysis*

Age category (years)	2-11	12-17	18-64	65+	Total	
Age distribution among patients ≥2 years	11.39%	8.47%	71.27%	8.87%	100%	
Number of patients by age**	111,087	82,608	695,096	86,509	975,300	
AD diagnosis rate by age	2.40%	1.14%	0.54%	0.69%		
Number of patients diagnosed with AD by age**	2,666	942	3,754	597	7,958	
TCI/TCs	% receiving TCI/TCs among diagnosed	50.30%	60.25%	65.14%	58.99%	
	Number of AD patients receiving TCI/TCs treatment**	1,341	567	2,445	4,706	
TCI Only	% receiving TCI among diagnosed	4.60%	7.13%	5.61%	2.28%	
	Number of AD patients receiving TCI treatment**	123	67	211	414	

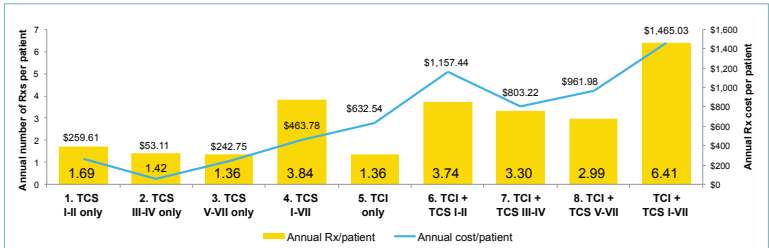
Key: AD – atopic dermatitis; BIM – budget impact model; RWTUC – real-world utilization and costs; TCI – topical calcineurin inhibitor; TCS – topical corticosteroid. * Results are used as inputs for the BIM. ** Estimated for a health plan with 1 million members, where 97.53% of the population is 2 years of age and older.

Table 2. Current market share, number of prescriptions per year, and payment per prescription from RWTUC Analysis*

	Current market share for TCI/TCs population	Current market share for TCI population	Rx per patient (annual)				Pay per Rx			
			TCI	TCS I-II	TCS III-IV	TCS V-VII	TCI	TCS I-II	TCS III-IV	TCS V-VII
1. TCS I-II only	22.84%	n/a	n/a	1.69	n/a	n/a	\$153.83	n/a	n/a	n/a
2. TCS III-IV only	40.54%	n/a	n/a	n/a	1.42	n/a	n/a	\$37.45	n/a	n/a
3. TCS V-VII only	9.63%	n/a	n/a	n/a	n/a	1.36	n/a	n/a	\$177.91	n/a
4. TCS I-VII**	18.19%	n/a	n/a	1.52	1.52	0.80	n/a	\$162.64	\$50.66	\$175.50
5. TCI only	2.20%	25.00%	1.36	n/a	n/a	n/a	\$463.44	n/a	n/a	n/a
6. TCI + TCS I-II	1.42%	16.11%	1.52	2.22	n/a	n/a	\$478.04	\$194.23	n/a	n/a
7. TCI + TCS III-IV	1.94%	22.09%	1.48	n/a	1.82	n/a	\$466.32	n/a	\$62.22	n/a
8. TCI + TCS V-VII	0.65%	7.37%	1.44	n/a	n/a	1.55	\$462.31	n/a	n/a	\$191.90
9. TCI + TCS I-VII**	2.53%	29.43%	1.68	1.82	1.84	1.08	\$485.45	\$183.16	\$64.64	\$184.88
Total	100%	100%								

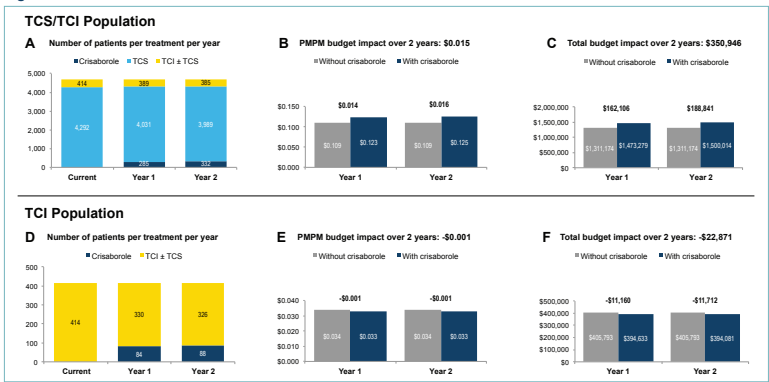
Key: AD – atopic dermatitis; BIM – budget impact model; n/a – not applicable; RWTUC – real-world utilization and costs; TCI – topical calcineurin inhibitor; TCS – topical corticosteroid. * Results are used as inputs for the BIM. ** Any multiple, excluding the strategies above.

Figure 2. Annual Per-Patient Prescriptions and Costs



Key: Rx – prescription; TCI – topical calcineurin inhibitor; TCS – topical corticosteroid.

Figure 3. BIM Results



Key: AD – atopic dermatitis; BIM – budget impact model; TCI – topical calcineurin inhibitor; TCS – topical corticosteroid.

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