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ORIGINAL RESEARCH

Atopic Dermatitis Treatments Before and After Initiation of Ruxolitinib Cream: 6-Month Follow-Up Analysis of a US Payer Claims Database

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Purpose: Many patients with atopic dermatitis (AD), a highly pruritic, relapsing, inflammatory skin disease, experience inadequate disease control. Ruxolitinib cream was approved in the US in September 2021 for the treatment of mild-to-moderate AD. This analysis describes treatment patterns before and after initiation of ruxolitinib cream among patients with AD.

Patients and Methods: This retrospective, observational study used medical and pharmacy claims data from the Healthcare Integrated Research Database (HIRD®) and included adults and adolescents (aged ≥12 years) with an AD diagnosis, a first claim for ruxolitinib cream (index date) between October 2021 and July 2022, and continuous enrollment in a commercial or managed Medicare plan for 6 months before and after the index date. Analyses were also conducted in a subset of patients with a history of more advanced AD therapy (ie, systemic therapies, phototherapy, or ultrahigh-potent topical corticosteroids). Data from 6 months before ruxolitinib cream initiation (baseline period) and after initiation (follow-up period) were summarized using descriptive statistics.

Results: Of 1,581 patients in the overall AD cohort, 749 had a history of more advanced AD therapy. During the follow-up period, 43.8% of patients did not receive any other AD treatment. Compared with baseline, fewer patients received topical corticosteroids (52.3% vs 30.4%), topical calcineurin inhibitors (13.9% vs 6.6%), and topical phosphodiesterase-4 inhibitors (4.4% vs 2.3%) during the follow-up period; slightly greater reductions were observed among the subset with a history of more advanced AD therapies. Oral corticosteroid use decreased from 20.9% to 15.5% overall and from 44.1% to 20.7% in the subset with more advanced baseline therapy. Among patients receiving biologics at baseline, 17.4% did not receive these treatments during the follow-up period.

Conclusion: These 6-month follow-up data suggest that initiating ruxolitinib cream for AD may reduce the overall need for other topical treatments, oral corticosteroids, and biologics.

Plain Language Summary: Ruxolitinib cream is a recently approved medicine used to treat atopic dermatitis (AD), a disease that causes itchy and dry skin. It is a topical Janus kinase inhibitor and not a steroid. We wanted to explore how the use of ruxolitinib cream affected the use of other medicines used to treat AD. Using medical and pharmacy insurance records, we found that patients used less of other treatments for AD after starting ruxolitinib cream.

Keywords: atopic dermatitis, Janus kinase, ruxolitinib cream, topical

Introduction

Atopic dermatitis (AD) is a chronic, inflammatory skin disease affecting 10% of children[1] and approximately 5% to 10% of adults[2,3] in the US. Patient quality of life is reduced by AD across severity levels, driven by symptoms of itching, sleep disturbance, and skin pain.[4] AD follows a heterogeneous course,[5] which necessitates multiple strategies for management of flares based on symptom severity, lesion location, and treatment history.[6,7] Topical therapies are collectively recommended as the mainstay of treatment; options available in the US since 2016 include corticosteroids, calcineurin inhibitors, and the phosphodiesterase (PDE)-4 inhibitor crisaborole.[7] However, topical corticosteroids are not

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recommended for sensitive areas and are associated with adverse events with prolonged use.[7] Furthermore, topical calcineurin inhibitors and crisaborole may cause local burning or stinging.[7] Patients who experience inadequate AD control with topical treatments may benefit from escalation to systemic therapies, such as the biologics dupilumab and tralokinumab that were both approved by the US Food and Drug Administration within the last several years.[6] However, the decision to initiate a systemic medication can be difficult owing to risks associated with immunosuppression,[8] as well as high costs for biologics,[9] especially when used as continuous therapy. Even with systemic therapy, patients may experience inadequate disease control.[10] As AD management is transforming based on the recent approvals of new topical and systemic treatments, there is a need to understand the effects of the newer treatment options in real-world practice, especially in the context of other treatments.

Janus kinases (JAKs) contribute to the pathogenesis of AD and itch by mediating proinflammatory cytokine signaling.[11,12] Ruxolitinib cream is a topical formulation of ruxolitinib, a selective inhibitor of JAK1 and JAK2,[13] that was approved by the US Food and Drug Administration in September 2021 for the treatment of mild-to-moderate AD in patients aged ≥12 years.[14] Two Phase 3 clinical trials (TRuE-AD1 and TRuE-AD2 [NCT03745638 and NCT03745651]) demonstrated the safety and efficacy of ruxolitinib cream when used continuously for 8 weeks to reduce signs and symptoms of AD and as-needed for longer-term disease control.[15,16] In TRuE-AD1 and TRuE-AD2, ruxolitinib cream resulted in significant improvements in itch, sleep, and work productivity versus vehicle (no active drug).[16,17] Post-marketing analyses based on the first year of approval in the US have confirmed that ruxolitinib cream is well tolerated, with a low incidence of application site reactions.[18] Thus, ruxolitinib cream may represent an effective nonsteroidal topical treatment option for patients with AD.

Despite the assessment of the safety and efficacy of ruxolitinib cream monotherapy in clinical trials, its role within the broader landscape of treatment options in real-world practice remains less explored.[19,20] As ruxolitinib cream emerges as a potential alternative to steroidal and systemic therapies, it is important to assess the extent of its effect on the use of other treatments. This study reports characteristics of early initiators of ruxolitinib cream and further examines AD treatment patterns prior to and following the initiation of ruxolitinib cream.

Methods

Data Source

This retrospective, observational study used administrative claims data from the Healthcare Integrated Research Database (HIRD®). The HIRD contains medical and pharmacy claims from a large, national commercial payor, representing over 80 million members across the US since 2006. A large proportion of members are commercially insured, with the remainder covered by managed Medicare. The 2020 HIRD population was representative of the 2020 US Census population in terms of sex, age, and geographic region of residence; the race/ethnicity distribution indicates slightly more non-Hispanic White members compared with the census.[21] The management of all data and study materials conformed with the Health Insurance Portability and Accountability Act (HIPAA) rules. A limited dataset, which excluded patient-identifying information, was used for all analyses, as defined by the HIPAA Privacy Rule. As the research involved a limited dataset in which there exists an agreement with the covered entities permitting this use, internal institutional guidelines exempted the research from ethics review based on US Health and Human Services Office for Human Research Protections regulations, including the HIPAA Privacy Rule. Carelon Research is a wholly owned subsidiary of Elevance Health and is a business associate of the affiliated Anthem health plans and has agreements in place with the Anthem health plans allowing them to conduct research using the data in the format of limited datasets in compliance with HIPAA (45 CFR 164.514(e)(4)(ii)).

Study Design and Patient Selection

The analysis included patients with a first pharmacy claim for ruxolitinib cream between October 1, 2021, and July 31, 2022; the first claim was defined as the index date. A baseline period was defined as 6 months before the index date, and the follow-up period was defined as the index date through 6 months post-index (Figure 1). Eligible patients were ≥12 years old and enrolled in a commercial or managed Medicare plan on the index date with continuous enrollment in a healthcare plan during the baseline and follow-up and a medical claim with an AD diagnosis (International Classification of Diseases, Tenth Revision [ICD-10]

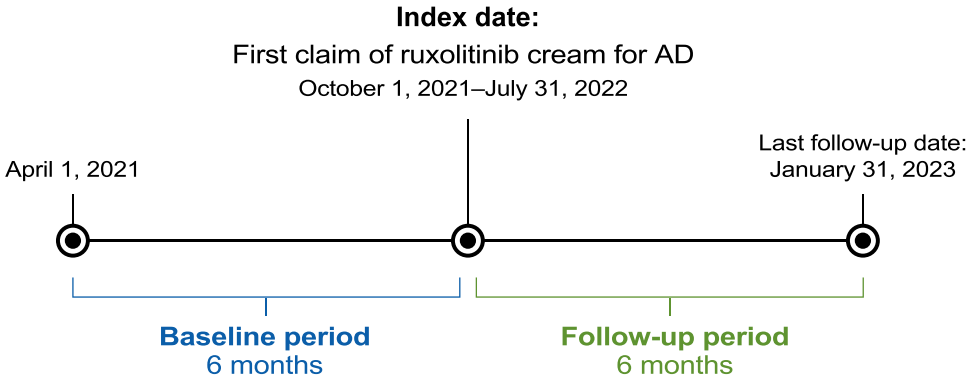

Figure 1 Study Design.
Abbreviation: AD, atopic dermatitis.

codes beginning with L20) during the baseline period or on the index date. Patients diagnosed with vitiligo (ICD-10 codes beginning with L80) during the baseline period were excluded because ruxolitinib cream is also approved for nonsegmental vitiligo.

In addition to the overall cohort of ruxolitinib cream users, a subset of patients with a history of more advanced AD therapy were also analyzed, defined based on a previously reported algorithm.[22] Patients in this subset had been treated with biologics, systemic corticosteroids, systemic immunosuppressants, phototherapy, or ultrahigh-potent topical corticosteroids during the baseline period.

Patient Characteristics and Outcomes

Demographic data (eg, age and sex) were collected based on enrollment files, except for race and ethnicity. Member-level race and ethnicity were derived from enrollment data, self-attestations, electronic medical record data, and algorithm-derived imputations based on name and geography; previous validation of this method demonstrated good concordance with self-reported data.[23] Comorbidities from the Elixhauser index[24] were assessed individually based on medical claims; for privacy and confidentiality reasons, substance abuse comorbidities were not reported. Other comorbidities of interest included allergic rhinitis, anxiety, asthma, atherosclerotic cardiovascular disease, attention-deficit/hyperactivity disorder, bipolar disorder, eosinophilic esophagitis, food allergies, heart failure, insomnia, ischemic stroke, myocardial infarction, obsessive compulsive disorder, schizophrenia, skin infections, and type 2 diabetes. Treatment patterns were assessed based on pharmacy claims. Treatments were categorized by classes of topical treatments (corticosteroids, calcineurin inhibitors, and PDE-4 inhibitors) and systemic treatments (biologics [ie, dupilumab and tralokinumab], oral corticosteroids, systemic immunosuppressants, and systemic JAK inhibitors [ie, abrocitinib and upadacitinib]). Assessed treatment patterns included use of treatment classes before and after ruxolitinib cream initiation, oral corticosteroid dosing, and changes in biologics use from baseline to follow-up. Cumulative oral corticosteroid dosing was calculated for each patient as the sum of all recorded doses (standardized to prednisone-equivalent dose) over the 6 months of follow-up.

Statistical Analysis

Descriptive statistics were reported for continuous and categorical data; no hypothesis testing was conducted. Analyses were conducted using the Instant Health Data platform (Panalgo, Boston, MA, USA), R version 4.3.2 (The R Foundation for Statistical Computing, Vienna, Austria), and Statistical Analysis Software Enterprise Guide version 9.3 (SAS Institute, Cary, NC, USA).

Results

Patients

A total of 1,581 patients with AD and ≥1 claim for ruxolitinib cream were included in this analysis (Figure 2). Of these patients, 749 were included in the subset of patients with a history of more advanced AD therapy use. Baseline

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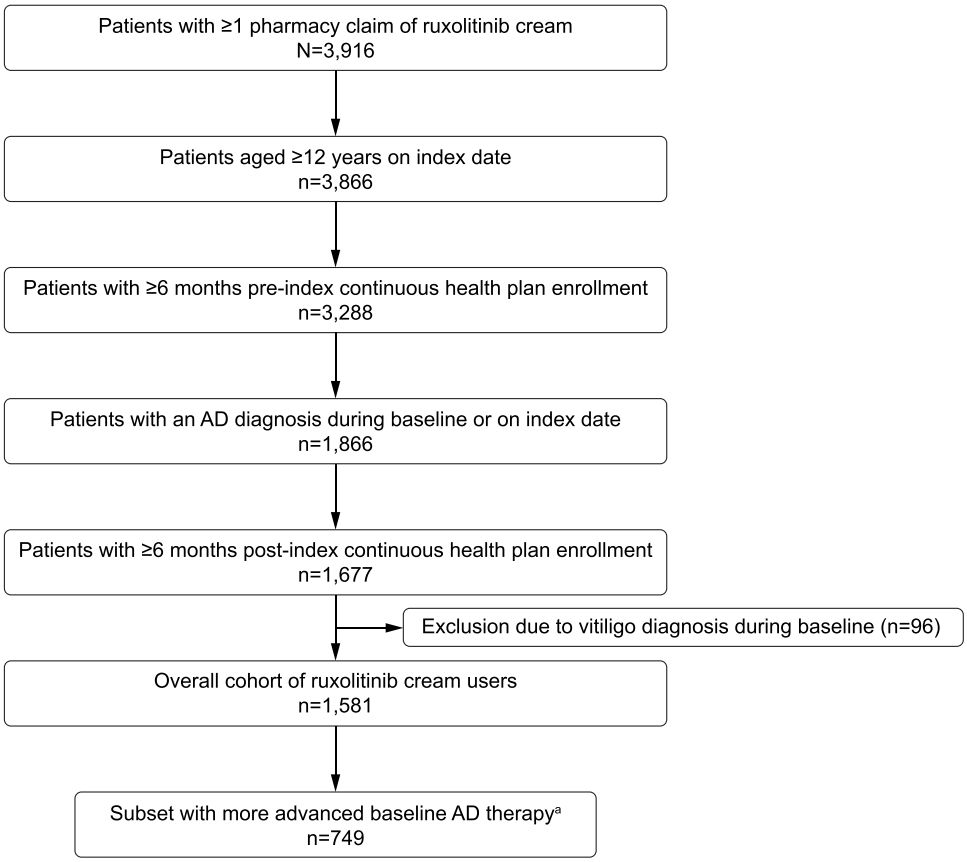

Figure 2 Patient Selection.
Note: [a]Patients in this subset had baseline use of biologics, systemic corticosteroids, systemic immunosuppressants, phototherapy, or high/ultrahigh-potent topical corticosteroids.
Abbreviation: AD, atopic dermatitis.

demographics and clinical characteristics are summarized in Table 1. In both the overall cohort and the subset with more advanced baseline AD therapy, approximately 10% of patients were adolescent and the majority were female. Allergic rhinitis, anxiety, hypertension, depression, chronic pulmonary disease, and asthma were observed in approximately 10% to 20% of patients at baseline in both analysis groups, with slightly higher prevalence in the subset with more advanced baseline AD therapy compared with the overall cohort. During the 6-month baseline period before ruxolitinib cream initiation, 57.4% of patients in the overall cohort received topical AD therapy, 19.6% received ultrahigh-potent topical corticosteroids, and 36.2% received systemic therapy. For the subset with more advanced baseline AD therapy, baseline treatment use was more common across most classes, with 71.4% of patients receiving any topical AD therapy, 41.4% receiving ultrahigh-potent topical corticosteroids, and 76.5% receiving systemic therapy.

Treatment Patterns

During the 6-month follow-up period after ruxolitinib cream initiation, the mean (SD) number of ruxolitinib cream fills was 1.6 (1.1) in the overall cohort and 1.7 (1.1) in the subset of patients with more advanced baseline AD therapy. Ruxolitinib cream monotherapy was observed during the follow-up period for 43.8% of patients in the overall cohort and 27.5% of patients in the subset with more advanced baseline AD therapy. Most patients in both groups did not receive another new class of AD treatment after the initiation of ruxolitinib cream (overall cohort, 72.0%; subset with more advanced baseline AD therapy, 73.6%).

Initiation of ruxolitinib cream was associated with reductions in the use of other topical therapies, including corticosteroids, calcineurin inhibitors, and PDE-4 inhibitors (Figure 3). Percent reductions from the 6-month baseline

Table 1 Baseline Demographic and Clinical Characteristics

Characteristic	Ruxolitinib Cream Users	
	Overall Cohort n=1,581	Subset with More Advanced Baseline AD Therapy n=749
Age, mean (SD), y	38.8 (17.0)	41.5 (17.0)
12–17 y, n (%)	186 (11.8)	66 (8.8)
18–44 y, n (%)	769 (48.6)	338 (45.1)
45–64 y, n (%)	538 (34.0)	295 (39.4)
65–74 y, n (%)	70 (4.4)	37 (4.9)
≥75 y, n (%)	18 (1.1)	13 (1.7)
Sex, n (%)		
Female	1,027 (65.0)	472 (63.1)
Male	552 (35.0)	276 (36.9)
Race or ethnicity, n (%)		
White	889 (56.2)	448 (59.8)
Black/African American	151 (9.6)	74 (9.9)
Hispanic or Latino, any race	128 (8.1)	52 (6.9)
Other[a]	183 (11.6)	72 (9.6)
Unknown	230 (14.5)	103 (13.8)
Elixhauser comorbidities,[b] n (%)		
Hypertension	231 (14.6)	137 (18.3)
Depression	193 (12.2)	89 (11.9)
Chronic pulmonary disease	188 (11.9)	113 (15.1)
Obesity	127 (8.0)	66 (8.8)
Comorbidities of interest,[c] n (%)		
Allergic rhinitis	246 (15.6)	145 (19.4)
Anxiety	242 (15.3)	128 (17.1)
Asthma	167 (10.6)	98 (13.1)
Skin infections	103 (6.5)	62 (8.3)
Type 2 diabetes	74 (4.7)	40 (5.3)
ADHD	72 (4.6)	39 (5.2)
ASCVD	55 (3.5)	31 (4.1)
Insomnia	50 (3.2)	27 (3.6)
Food allergies	36 (2.3)	21 (2.8)
Baseline AD therapy,[d] n (%)		
Topical therapy	908 (57.4)	535 (71.4)
Topical corticosteroids	827 (52.3)	499 (66.6)
Low potency	174 (11.0)	101 (13.5)
Moderate potency	441 (27.9)	221 (29.5)
High potency	166 (10.5)	78 (10.4)
Ultrahigh potency	310 (19.6)	310 (41.4)
Topical calcineurin inhibitor	220 (13.9)	133 (17.8)
Topical PDE-4 inhibitor	70 (4.4)	37 (4.9)
Systemic therapy	573 (36.2)	573 (76.5)
Biologics	298 (18.8)	298 (39.8)
Oral corticosteroids	330 (20.9)	330 (44.1)
Any immunosuppressants[e]	23 (1.5)	23 (3.1)
Janus kinase inhibitors	5 (0.3)	5 (0.7)

Notes: [a]Other includes Asian, American Indian/Alaska Native, or >1 race reported. [b]Comorbidities occurring in ≥8.0% of patients in either cohort at baseline; for privacy and confidentiality reasons, comorbidities related to substance use were not reported. [c]Comorbidities occurring in ≥2.5% of patients in either cohort at baseline. [d]Patients could have received >1 baseline AD therapy. [e]Immunosuppressants included azathioprine, mycophenolate mofetil, cyclosporine, or methotrexate.
Abbreviations: AD, atopic dermatitis; ADHD, attention-deficit/hyperactivity disorder; ASCVD, atherosclerotic cardiovascular disease; PDE-4, phosphodiesterase-4.

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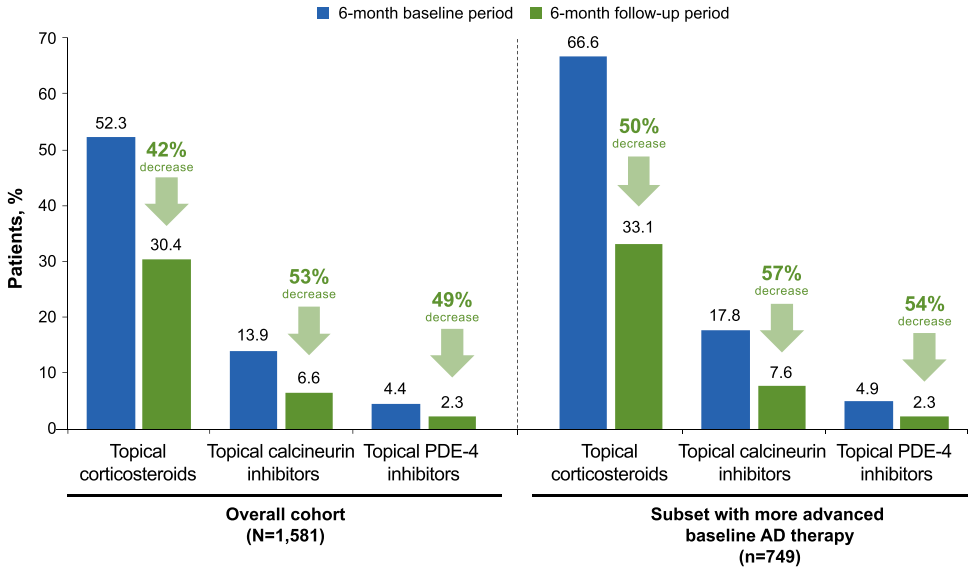

Figure 3 Topical Treatment Use for AD Before and After Initiation of Ruxolitinib Cream.
Abbreviations: AD, atopic dermatitis; PDE-4, phosphodiesterase-4.

period to the 6-month follow-up period were >40% for all 3 medication categories in the overall cohort and ≥50% in the subset of patients with more advanced baseline AD therapy.

Oral corticosteroid use decreased in the overall cohort from 20.9% of patients during baseline to 15.5% during follow-up. A larger change was observed in the subset of patients with more advanced baseline AD therapy, with oral corticosteroid use decreasing from 44.1% of patients during baseline to 20.7% during follow-up. Mean cumulative prednisone-equivalent dose among all patients over the 6-month follow-up period decreased by 31.5% in the overall cohort and 49.4% in the subset with more advanced baseline AD therapy (Figure 4).

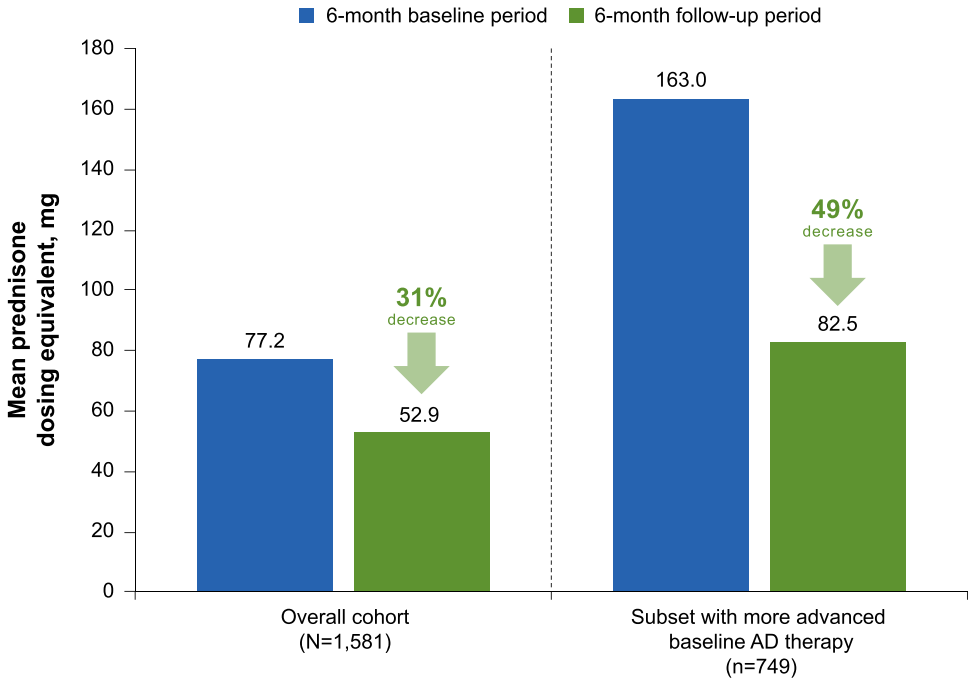

Figure 4 Oral Corticosteroid Use Before and After Initiation of Ruxolitinib Cream.
Abbreviation: AD, atopic dermatitis.

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Table 2 Biologics Use for AD Before and After Initiation of Ruxolitinib Cream

	Biologic Free During Follow-Up, n (%)
Overall cohort (N=1,581)	
Biologic experienced (n=298)	52 (17.4)
Biologic naive (n=1,283)	1,184 (92.3)
Subset with more advanced baseline AD therapy (n=749)	
Biologic experienced (n=298)	52 (17.4)
Biologic naive (n=451)	399 (88.5)

Abbreviation: AD, atopic dermatitis.

Among 1,283 biologic-naive patients during the 6-month pre-index period, 92.3% did not receive biologics during the 6-month follow-up period, and the remaining 7.7% initiated biologics (Table 2). Of the biologic-naive patients who were in the subset with more advanced baseline AD therapy, 88.5% did not receive biologics, and 11.5% initiated biologics during the follow-up period (Table 2). Among 298 patients with claims for biologics during the 6-month baseline period (all of whom were in the more advanced baseline therapy group), 52 (17.4%) did not continue biologics during the 6-month follow-up period.

Discussion

In this retrospective, observational study, AD treatment patterns were assessed for adult and adolescent patients who initiated ruxolitinib cream, with analyses also performed in a subset of patients who had previously received more advanced AD therapy. During the 6 months following ruxolitinib cream initiation, both the overall cohort and the subset showed a decrease in utilization of other AD treatments relative to the baseline period. Almost half of patients in the overall cohort did not receive any other AD treatment during the follow-up period. Use of several classes of AD treatment decreased from baseline to follow-up, including for topical and oral corticosteroids; an approximately 50% decrease was observed in oral prednisone-equivalent dose in the subset with more advanced baseline AD therapy. Thus, these early assessments suggest that initiating ruxolitinib cream may reduce the overall need for other AD therapies.

The decreased use of AD therapies observed in this study may offer several potential benefits to patients. Topical corticosteroids, especially at higher potencies, are not recommended for long-term use or in sensitive areas[7] and are associated with decreased skin thickness[25] as well as possible systemic adverse events.[26] The nonsteroidal topical agents, calcineurin and PDE-4 inhibitors, are associated with application site reactions, such as burning or stinging.[27,28] In terms of systemic treatments, it was notable that oral corticosteroid use decreased after ruxolitinib initiation both in terms of the number of patients and mean dose. Systemic corticosteroids, despite prevalent use for patients with moderate-to-severe AD, are not recommended in most cases by several guidelines owing to a largely unfavorable risk-benefit ratio, especially for long-term use.[6,29] Therefore, patients who reduced or eliminated oral corticosteroid treatment after ruxolitinib cream initiation may have been able to transition to a treatment regimen that is more aligned with guidelines.

Escalation to biologics is of interest as these patients are on a high-cost regimen of continuous therapy.[9] In the present analysis, approximately one-fifth of patients with baseline biologics were no longer treated with biologics during follow-up, whereas approximately one-tenth of patients without baseline biologics initiated them during follow-up. The availability of ruxolitinib cream as an option that may delay or prevent escalation to biologics is relevant to patients, who tend to rank route of administration (ie, topical or oral vs injection) as an important attribute in their product preferences.[30,31] Additional burdens of biologics include high cost and potential need for continuous maintenance injections.[9] Although further research is required to assess treatment patterns of patients who may need systemic therapy, this early assessment suggests that ruxolitinib cream could provide an alternative to the escalation to systemic biologics.

This study was subject to limitations typically associated with database analyses, such as the use of nonrandomized data, incomplete or missing data, and potential coding errors. Disease severity and other characteristics could not be measured from claims data, although they are important factors influencing treatment decisions. The single-arm study design limits the ability to directly attribute the observed effects to the initiation of ruxolitinib cream. The included study

population may limit the generalizability of the outcomes. For example, the study was largely based on commercial health insurance coverage, and these patients may have different characteristics than those with public or no health insurance coverage. Additionally, the requirement of continuous enrollment for 6 months before and after the index date could influence generalizability.

Conclusion

These data describing reductions of other AD treatments within 6 months of ruxolitinib cream initiation provide additional evidence for its effectiveness as a therapeutic option for adults and adolescents with AD. Nearly half of the patient population did not need additional AD treatments, and topical and oral corticosteroid use decreased during the follow-up period. Moreover, >90% of biologic-naive patients did not initiate biologic use, and nearly one-fifth of those previously on biologics discontinued their use during the follow-up period. These findings suggest that ruxolitinib cream could limit the use of other AD therapies, including topical/oral corticosteroids and biologics, potentially simplifying treatment regimens for patients.

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Disclosure

Dr Liu, Dr Sturm, and Dr Patadia are employees and shareholders of Incyte Corporation. Dr Desai, Ms Teng, Ms Stockbower, and Dr Willey are employees of Carelon Research, which received funding from Incyte Corporation to perform this research. Dr Desai, Ms Teng, and Dr Willey are shareholders of Elevance Health, the parent company of Carelon Research. The authors report no other conflicts of interest in this work.

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