

# Under-Treatment of Patients with Moderate to Severe Psoriasis in the United States: Analysis of Medication Usage with Health Plan Data

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## ABSTRACT

**Introduction:** Psoriasis is a chronic inflammatory disorder with significant morbidity and mortality, but a persistent gap appears to exist for the adequate treatment of patients with moderate to severe disease. As the extent of under-treatment is unknown, we attempted to determine overall treatment patterns and estimate under-treatment using a large database.

**Methods:** Data from the US National Health and Wellness Survey was used to estimate the proportion of patients with mild, moderate or

severe psoriasis. The proportion with moderate to severe disease was estimated by excluding those with mild disease, and projecting this to the total insured US population, weighted by age and gender. Using US health plan claims data, patient totals by treatment type were determined between October 1, 2007 and September 30, 2012. Patients had to be continuously enrolled in a health plan and be  $\geq 18$  years at the end of the analysis window. Psoriasis was confirmed if patients had at least one claim of any type of psoriasis except psoriatic arthropathy (ICD-9 code 696.1). A monthly treatment history, classified by biologic, traditional oral systemic, phototherapy and topical therapy, was recorded for each patient.

**Results:** There were an estimated 1.7 million insured US patients with moderate to severe psoriasis. Of these, 1 million (59%) were not treated for their condition in the preceding year. Among 695,488 patients who were treated for psoriasis in the preceding year, 346,201 were currently receiving treatment and 349,287 had lapsed treatment. Of the patients lapsed and currently treated in this period, the numbers who received each treatment type were 156,409 (biologic), 222,657 (traditional oral systemic),

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22,911 (phototherapy), and 293,511 (topical). A limitation of the study was that only insurance claims were analyzed.

**Conclusion:** Moderate to severe psoriasis remains persistently untreated or under-treated. We suggest that potential barriers preventing access to care be explored.

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**Keywords:** Biologics; Healthcare claims data; Phototherapy; Psoriasis; Real-world data; Topical therapy; Traditional oral systemics

## INTRODUCTION

Psoriasis is a chronic inflammatory disorder with significant morbidity and mortality. It affected approximately 7.4 million US adults in 2013, with an estimated prevalence of 3.2% [1]. The financial burden of psoriasis is considerable, with an estimated annual cost to the US of \$112 billion (2013 USD) [2]. The burden also extends to physical, psychological, and quality of life impairment [3].

Current treatment guidelines for psoriasis recommend topical therapies for mild disease, either as monotherapy or in combination with phototherapy, and traditional oral systemic agents (e.g., methotrexate), or biologic agents (e.g., anti-tumor necrosis factor inhibitors) for moderate to severe disease [4–8]. Phototherapy is also recommended as one of the therapies for moderate to severe psoriasis [9]. However, despite guidelines, inadequate treatment of patients, absence of treatment, or unsatisfactory disease control, remain key concerns for healthcare professionals [10]. Recent survey data suggested that a gap persists in the appropriate treatment of patients with moderate to severe psoriasis [11, 12].

Patients with psoriasis tend to cycle through multiple treatment options, which are often added, switched, re-started, or discontinued, but real-world data describing treatment patterns and treatment flow are scarce. In surveys by the National Psoriasis Foundation (NPF) involving 5604 patients between 2003 and 2011, the proportion of untreated patients was approximately one-third each in those with mild, moderate, or severe psoriasis, respectively [10]. Determining these patterns is important to the prescribing physician because it provides the foundation for understanding the treatment journey that patients undertake in accessing relief from this distressing condition.

Health claims databases provide an appropriate source of insight into the management of psoriasis as they capture information from healthcare professionals who are caring for individual insured patients, including records of diagnoses, prescriptions and procedures, dates of prescription fills and refills, treatment changes, and gaps where no prescription has been given. These databases are typically large and, therefore, representative of the regional or national population.

We used health plan claims data to determine overall treatment patterns and areas of under-treatment in insured US patients with moderate to severe plaque psoriasis over a 5-year period. In this study, we investigated whether patients with moderate to severe psoriasis are under-treated.

## METHODS

### Classification of Disease Severity

Health claims data do not include information on severity; therefore, this information was obtained by estimating the proportion of mild psoriasis

patients out of the total psoriasis population included in the US National Health and Wellness Survey [11]. The National Health and Wellness Survey is a large, international, patient-self-reported database of general health as well as disease-specific information, collected annually; the most recent sample includes information from the 2009 survey of 75,000 US patients [13]. To obtain the proportion of patients with moderate to severe psoriasis, patients with mild disease were excluded. Respondents in this survey self-reported their psoriasis severity having been asked the question: “According to the NPF, the palm of the hand equals 1 percent of the skin. Thinking about this, please estimate the percent of your body surface your psoriasis currently affects, 1 Mild (less than 3% body coverage), 2 Moderate (3–10% body coverage), 3 Severe (more than 10% body coverage).”

### Filtering Process for Comorbidities

To correct for subjects with, and those treated for, related comorbidities (e.g., psoriatic arthritis), patients with certain concurrent inflammatory conditions were retained on a fair-share basis (e.g., half of patients with an additional inflammatory condition and one-third of the patients with two additional inflammatory conditions were retained).

### Data Sources and Patient Population

With regard to the insured population, longitudinal US health plan claims data were obtained from IMS Health (LifeLink PharMetrics Plus™, Waltham, MA, USA) covering patients continuously enrolled in covered commercial healthcare insurance plans for the 5-year period from October 1, 2007 to September 30, 2012. To be eligible for inclusion, data were from patients aged 18 years or older at the end of this analysis

window. All data obtained from this source were Health Insurance Portability and Accountability Act compliant and exempt from institutional review board approval.

Patients were considered to have psoriasis if they had at least one claim listing International Classification of Diseases, Ninth Revision (ICD-9) code 696.1 (“all types of psoriasis except psoriatic arthropathy”) during the 5-year analysis window. Patients were included if they had continuous longitudinal data available (i.e., had been continuously enrolled for 5 years in any of the covered plans and had gender and age data available). Patients with a gap in enrollment information were excluded.

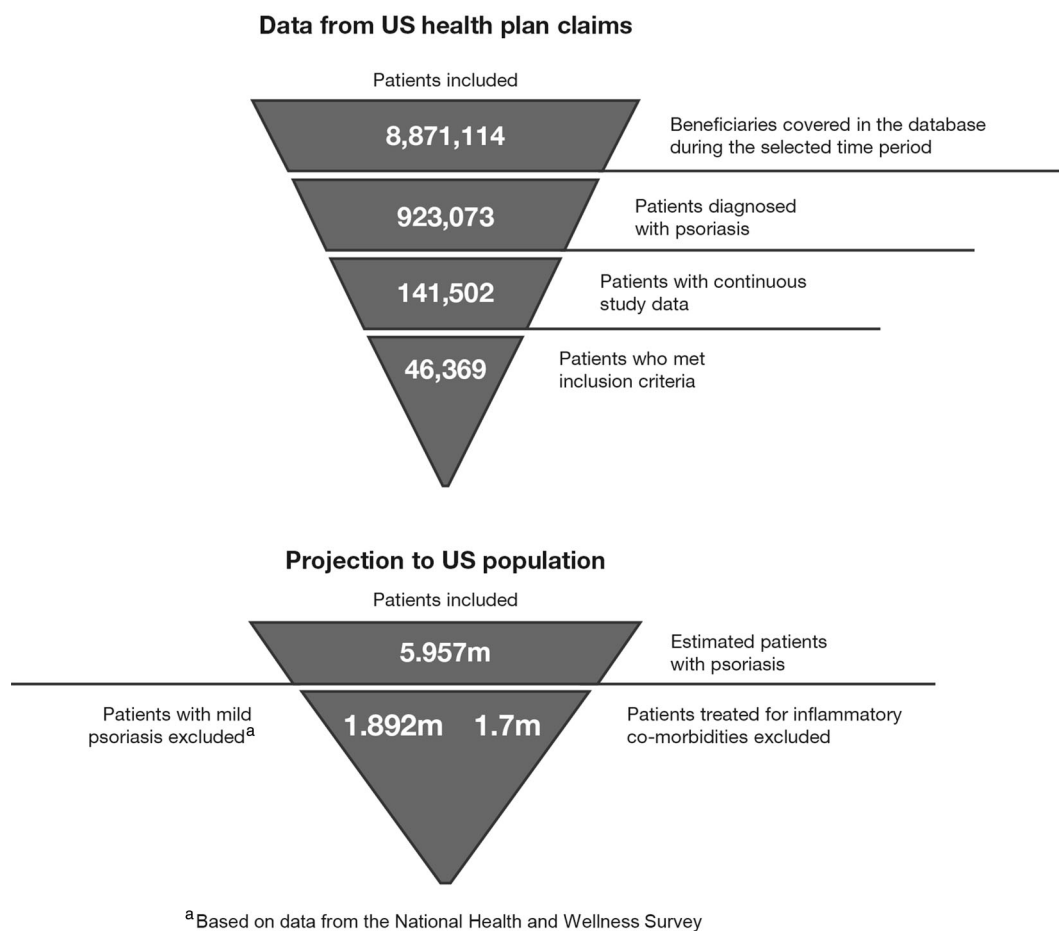
### Projection to the US Population

Based on the proportion of patients with psoriasis in the health plan claims database, we projected patient numbers to reflect the total insured US population [14] (Fig. 1). Collation of health-plan claims created a large sample that required weighting adjustments to be applied on the basis of age and gender to correct for bias and non-sampling [15].

Total disease load was calculated by extrapolating from the psoriasis population, diagnosed by ICD-9 code 696.1, to include undiagnosed patients, previously reported as 0.4% of the US population [16]. No confidence intervals were available from the latter source, and all estimates in this investigation were calculated without rounding to provide granular information.

### Data Processing

All drugs and procedures of interest (Table 1) were processed to construct a treatment history for each patient. Definitions of terms are listed in Table 2. Standardized days of service



**Fig. 1** Patients and projection to US population

(duration) were set for each prescription but not for procedures (Table 3).

Given that most patients were not fully compliant with treatment, we considered both the duration of treatment and a grace period. Treatment was categorized by month, such that if the claim date (date the prescription was taken to the pharmacy or the procedure was administered) plus days of service (minimum 31 days) plus 61 days grace extended on to or beyond the 15th of a month, treatment was recorded for that month. The number of days grace (31 days) required to meet high levels of continuous use was similar across different treatment classifications (Fig. 2).

When a prescription/procedure began before the end of a previous prescription/procedure for the same drug, the newer prescription took precedence and the remainder of the old prescription was disregarded. If two or more biologic prescriptions were in the same month, the one with the most recent start date was retained and the other was excluded.

### Treatment Categories

Treatments for all patients were identified on a monthly basis to permit the full treatment history to be assessed.

**Table 1** Drugs and treatments of interest in the study

<b>Biologic</b>	<b>Traditional oral systemic</b>	<b>Topical</b>
<b>Licensed for psoriasis</b>	<b>Traditional oral systemics of interest</b>	<b>Phototherapy</b>
Adalimumab	Acitretin	PUVA
Etanercept	Cyclosporine	UVB
Infliximab	Methotrexate	
Ustekinumab	Prednisone	
<b>Other biologics</b>	<b>Other traditional systemics</b>	<b>Other topical</b>
Abatacept	Azathioprine	Various
Alefacept ( <i>Withdrawn</i> )	Hydroxychloroquine	
Anakinra	Hydroxyurea	
Certolizumab pegol	Isotretinoin	
Efalizumab ( <i>Withdrawn</i> )	Leflunomide	
Golimumab	Mycophenolate mofetil	
Rituximab	Sulfasalazine	
Tocilizumab	Thioguanine	

*PUVA* psoralen and ultraviolet A therapy; *UVB* ultraviolet type B therapy

**Table 2** Definition of terms

<b>Term</b>	<b>Definition</b>
Naïve	A patient who did not have a treatment of interest at a given time point but had a claim with a psoriasis diagnosis (ICD-9 code 696.1) at some point during the analysis window
Days of service	Length of period of treatment or procedure awarded by the prescription (31 days if not recorded or <31 days). Procedures were assigned 31 or 61 days of service
Grace period	Additional 61 days added to days of service to account for poor compliance/adherence/concordance and to prevent very short switches out of and back into treatment
Lapsed	A patient who received a treatment of interest during the analysis window but was not on a treatment of interest at a given time point beyond the grace period
Lapsed biologic/systemic-experienced	Patients who had previously received a traditional biologic or systemic treatment but were only receiving topical treatment at a given time point beyond the grace period
Compliance	Adherence to treatment plan during the analysis window
Switch	Change in treatment status (i.e., starting, re-starting, or changing treatment)
Untreated	Not treated in the 5-year window with any of the drugs of interest

*ICD-9* International Classification of Diseases, Ninth Revision

**Table 3** Standardized duration of prescriptions (days of service)

Prescription	Duration <sup>a</sup> (days)
Adalimumab	31
Alefacept	84
Cyclosporine	31
Efalizumab	84
Etanercept	31
Infliximab	56
Methotrexate	31
Phototherapy	31
Triamcinolone	31
Ustekinumab <sup>b</sup>	84

<sup>a</sup> All prescriptions were allocated a minimum duration of 31 days

<sup>b</sup> Prescriptions were set to 84 days due to the erratic nature of the prescriptions observed in the data

Treatments were classified in the mutually exclusive hierarchy of biologic, traditional oral systemic, phototherapy, topical, lapsed, or naïve, as defined in Table 2. A treatment group that was higher in the hierarchy could include concurrent treatment with a therapy in a lower group in the hierarchy (e.g., a biologic patient also receiving phototherapy and topical therapy). Any patients treated with a biologic at any time during our 5-year analysis were retained. Traditional oral systemic patients were categorized as those with or without biologic experience at a point in time (e.g., a patient taking a traditional oral systemic who had previously taken a biologic during the 5-year timeframe was categorized as a traditional oral systemic patient with biologic experience). The lapsed patient group was divided into those with previous biologic exposure, traditional oral systemic agent exposure, and any biologic or traditional oral systemic exposure.

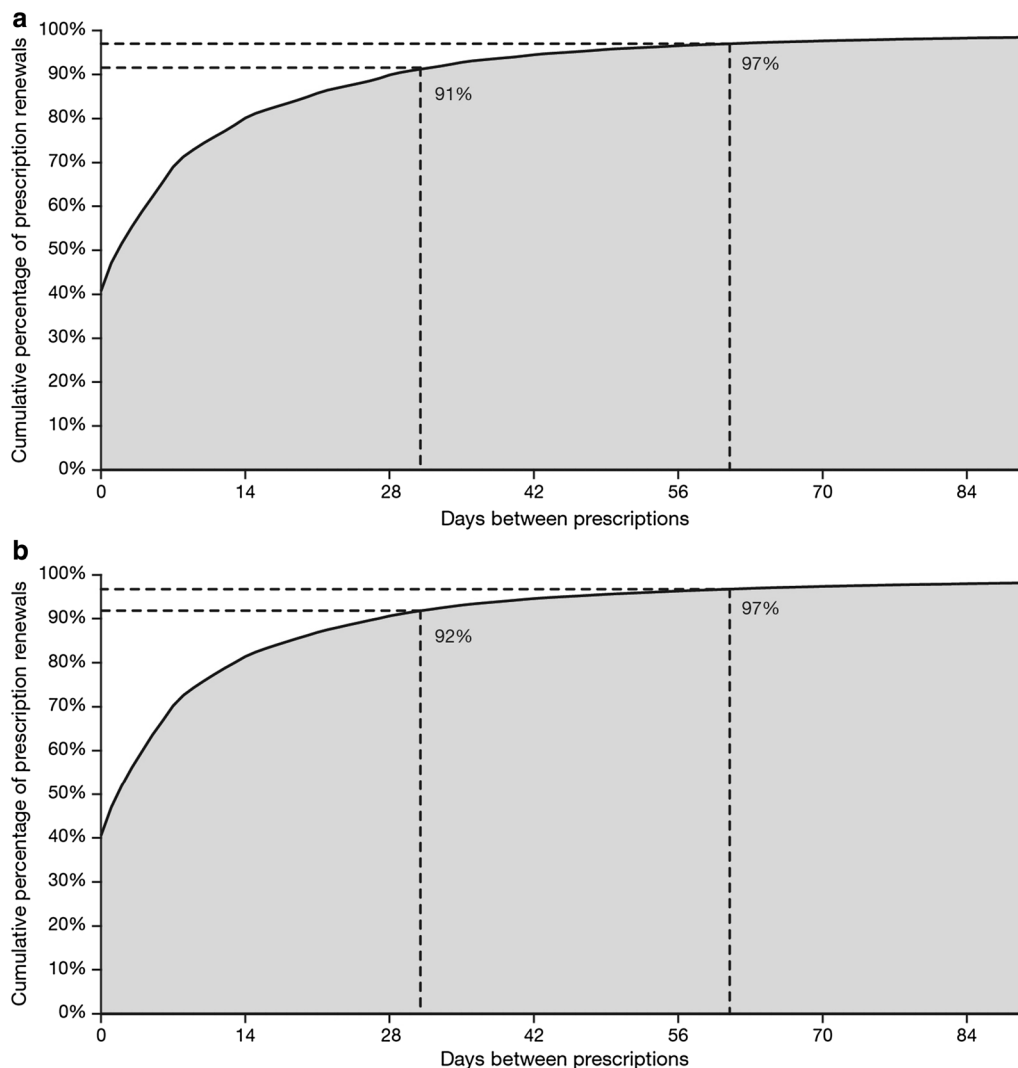
## RESULTS

### Patient Population

In the 5-year analysis window, health plan claims data identified 8,871,114 continuously enrolled patients, 923,073 (10.4%) of whom were diagnosed with psoriasis (ICD-9 code 696.1). Among these patients, 141,502 (15.3%) had continuous longitudinal data available and 46,369 (5.0%) met all of the inclusion criteria (Fig. 1). During the 5-year period, approximately 2.9 million prescriptions were recorded, with the most common being topical treatment (1.7 million prescriptions) and etanercept (0.4 million prescriptions), followed by methotrexate, adalimumab, and acitretin.

During the analysis period, the number of patients with psoriasis was highest in the sixth to seventh decade of life and then declined (Fig. 3). The number was higher in females than males, attributable to women below the age of 40 years; after 40 years of age, the numbers with psoriasis were similar in both genders. Also, as the population aged, a higher proportion of patients acquired medical insurance. At younger ages, more women than men were identified with psoriasis, although the difference narrowed up to age 60 years and then disappeared (Fig. 3).

The eligible population of 46,369 was projected on to the US population with a resulting estimate of 5,957,740 patients with psoriasis. Assigning disease severity by treatment types, excluding patients with mild disease (4,065,721) and those prescribed treatment for a related inflammatory comorbidity (191,753), resulted in an estimated 1,700,266 insured patients with moderate to severe psoriasis in the 5-year analysis window (Fig. 4). Of these, 546,814 (32.2%) were diagnosed but not treated.



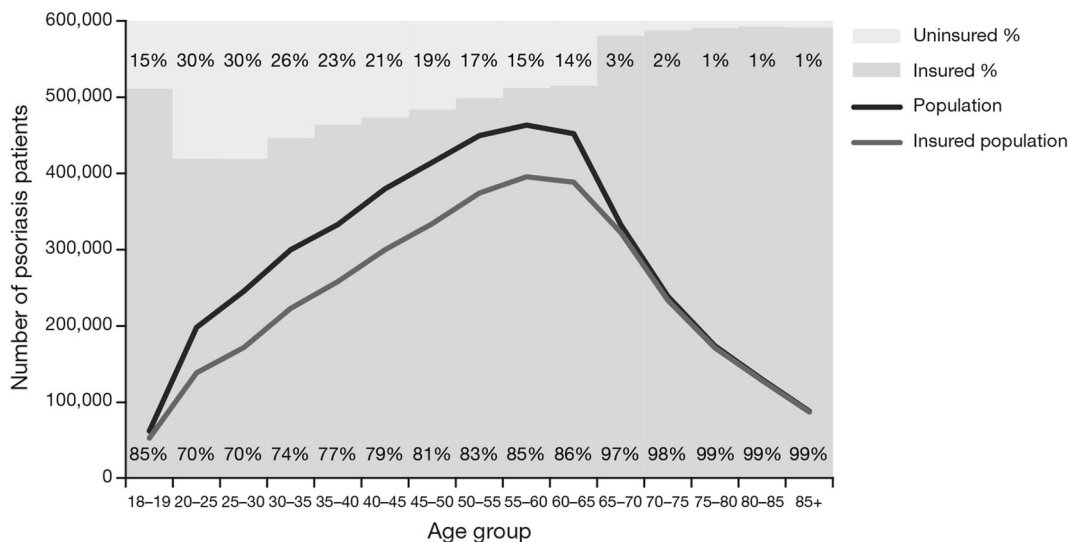
**Fig. 2** Number of days grace required to meet high levels of continuous use. Graphs show the cumulative percentages of **a** etanercept and **b** methotrexate prescription renewals (30-day prescriptions) over time (days since the end of the last prescription)

In the year prior to September 2012, there were 346,201 (of the 695,488 treated patients) who were currently receiving treatment for psoriasis and another 349,287 who had lapsed treatment. Furthermore, of the patients treated (lapsed + currently treated) in the prior year, 156,409 (22.5%), 222,657 (32.0%), 22,911 (3.3%), and 293,511 (42.2%) received a biologic, traditional oral systemic, phototherapy, or a topical treatment, respectively (Fig. 4). Most (83%) of the 132,931 patients with psoriasis currently receiving a biologic were on biologic

monotherapy, with 17% receiving a combination of a biologic and systemic therapy, which was consistent over the analysis period.

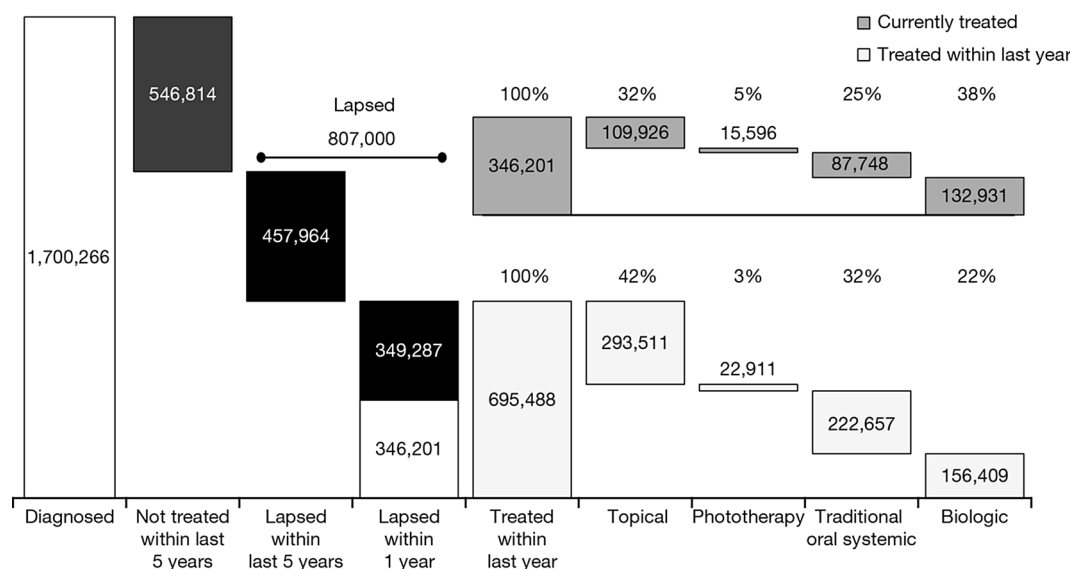
**Longitudinal Data**

The available longitudinal data indicated an increase in the use of all treatment types from September 2008 to September 2012 with increases of 10.5, 4.7, 6.0, and 6.9% in biologic, traditional oral systemic, phototherapy, and topical treatments, respectively (Fig. 5).



**Fig. 3** Weighted number of patients with psoriasis (in 2011) by age category in the total population and insured US population. Weighting was by age and gender to the US insured population using US census data and numbers

of people of each age and gender enrolled in the health plan database. Solid bars show the proportion of patients with and without insurance in each age category



**Fig. 4** Projected insured US population diagnosed with moderate to severe psoriasis. Bars show proportions in each treatment category

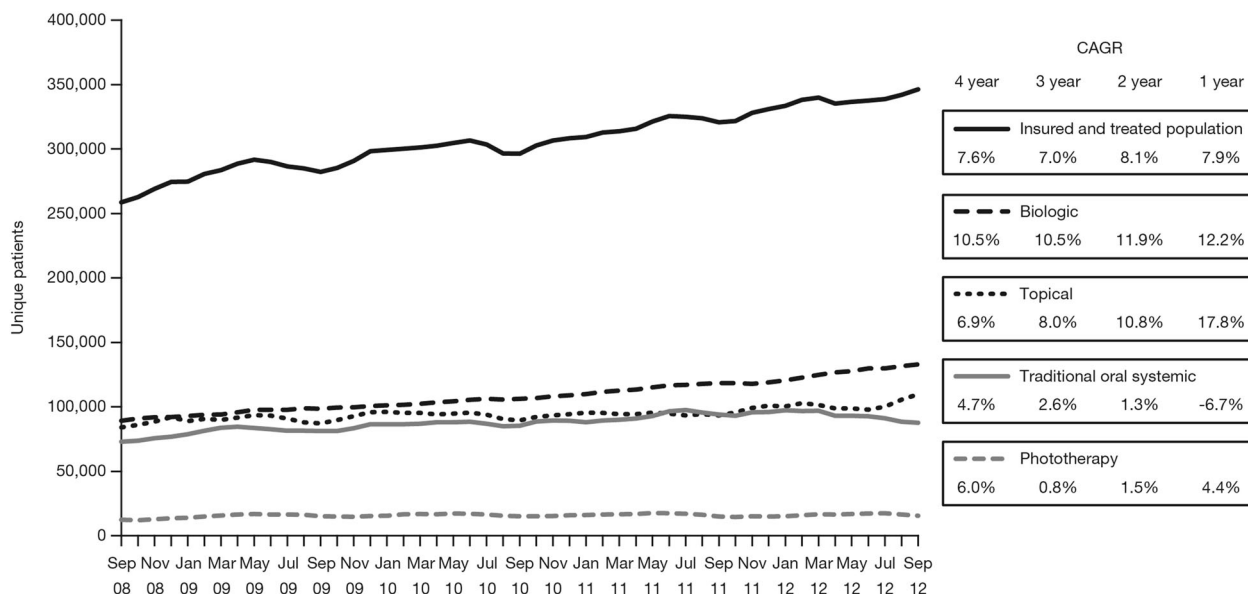
**Treatment Dynamics**

In the year prior to September 2012, an estimated 438,000 patients stopped their psoriasis treatment, another 384,000 re-started a psoriasis treatment, and 807,000 experienced a lapse in treatment (currently unpublished).

**DISCUSSION**

Our analysis is one of the first systematic investigations to use health plan claims data to examine the number of patients with moderate to severe psoriasis and patterns of treatment in the US longitudinally over a 5-year





**Fig. 5** Longitudinal data showing trends in the use of four treatment types for moderate to severe psoriasis from September 2008 to September 2012. CAGR compound

annual growth rate. Patients receiving topical therapy who were exposed to traditional oral systemic treatment were classified as “lapsed”, as defined in Table 3

period. This was achieved by identifying an eligible population of 46,369 insurance patients with moderate to severe disease and projecting this cohort to reflect the estimated 5.9 million insured US patients with psoriasis, of whom 1.7 million had moderate to severe disease. Although only around 1% of patients fulfilled all inclusion criteria, the resultant >46,000 patients represents a large patient population. The weighted estimate of 5.9 million represents 2.3% of the total US insured population (2012) of 206.2 million [17].

In the 5-year period, approximately one-quarter of patients (0.46 million) had received, but subsequently lapsed, from their treatment. The characteristics of the lapsed from treatment group have been investigated in a separate analysis (currently unpublished). One-third appeared to be untreated, as shown by the 0.55 million who were diagnosed but not treated—a proportion that is worthy of further investigation. Untreated patients never received

any of the specified drugs of interest in the 5-year window.

The proportion who were untreated was comparable with that identified by the NPF biannual surveys between 2003 and 2011, although different methodology was used (i.e., claims data vs. survey questionnaires). Estimates were between 24% and 35% for untreated moderate psoriasis and between 9% and 30% for untreated severe psoriasis in the NPF surveys [10]. In contrast to results from the NPF surveys, phototherapy was the least frequently used category of treatment (NPF: 33% peak in 2014 vs. 8% in the preceding year in our study), although the two analyses were not directly comparable. This difference may be due to the limited visibility of phototherapy within the claims database. The most frequently used treatment in the present study was topical therapy alone (74%) compared with approximately one-third (30%) of NPF survey patients with moderate psoriasis and one-fifth

(21%) with severe psoriasis [10]. The reason for the difference may be methodological or attributed to the one-off nature of topical therapy use.

Including patients treated within the preceding year and patients who were currently treated, biologics and traditional oral systemic therapies accounted for 60% ( $n = 289,340$ ) and 55% ( $n = 310,405$ ) of treatments, respectively. We observed that, although the use of biologics was growing, there remained a consistent proportion of patients on traditional oral systemic drugs. Overall, 60 different treatment types were recorded in the database, indicating the complexity and variability of patient disease loads.

When selecting a therapy, the clinician has to account not only for the benefit-risk profile of the prescribed medication but also patient preferences and payor procedures. Reimbursement impacts treatment decisions and the availability of oral and injectable alternatives is crucial to meet patients' needs and insurance coverage. In a published study, patients preferred oral therapy to phototherapies in a structured interview setting [18]. Patients with longer disease duration attached greater importance to duration of benefit, whereas patients on oral therapy were more concerned with magnitude of benefit in a conjoint analysis study [19]. Treatment guidelines recommend topical therapy for mild disease, yet topical treatment was either currently being used in 32% of patients or had been used in the previous 12 months (42%) in our analysis of patients with moderate to severe disease, suggesting that patients were receiving inadequate therapy, based on the claims data.

An advantage of analyzing claims data is the ability to monitor the start, end, and re-start of

a treatment as well as the switch from one treatment to another. The dynamics of treatment transitions have been investigated in a separate analysis (currently unpublished).

Health claims data track patients individually from clinics based on insurance coverage. Population estimates are relevant to the present analysis in that they are also individual-based. The proportion of moderate to severe patients with psoriasis may be higher in estimates of clinic samples than in the general population. We estimated the number of patients with moderate to severe psoriasis using claims data from a 5-year timeframe. In our investigation, there was no visibility of uninsured patients and treatments not associated with a claim. In the uninsured population, the burden may be particularly pronounced in the areas of non-treatment and under-treatment. Furthermore, we calculated total disease load by extrapolating from the number of patients diagnosed with psoriasis to include undiagnosed patients using a population-based approach [16]. We acknowledge that this did not align perfectly with the population we analyzed, but was the best source of data available on the undiagnosed population in the US.

We assumed that patients who were prescribed treatment actually went on to take the medication. Furthermore, we included grace periods to take into account discontinuous prescriptions. However, topical treatment and phototherapy may be underestimated in this analysis in cases when the use of both therapies lies outside the recordable scope of a claims database (e.g., the use of an over-the-counter topical treatment or subsequent use of phototherapy at home).

Although we chose the ICD-9 code 696.1, which encompassed all types of psoriasis except psoriatic arthropathy, there was still the

potential for misclassification since the 696.1 code is not specific to plaque psoriasis. We excluded other 696 ICD-9 codes to minimize the level of similar, non-plaque psoriasis indications.

The true extent of the under-treatment among the psoriasis population is likely even greater than in this analysis, which examined only the insured population. In the current healthcare environment, the uninsured and the newly insured patients with psoriasis, who have yet to gain access to providers with expertise in treating psoriasis, comprise a large proportion of the overall psoriasis population. Therefore, in the US, the under-treatment of patients with moderate to severe psoriasis is unfortunately highly prevalent and severe.

## CONCLUSION

In conclusion, this large health-plan-claims-based study showed that 40.9% of 1.7 million eligible US patients were receiving therapy for moderate to severe psoriasis in the 12 months up to September 2012. In that period, in approximately half (50.2%) of patients, treatment lapsed. Of those currently treated or treated within the last year, 42% had received topical therapy only. Our findings indicate that under-treatment of psoriasis is common, and, therefore, we suggest that the potential barriers preventing patients from accessing care, and the reasons for under-treatment, should be explored in future studies.

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scientific discussion of the data, its interpretation, and the development of the associated manuscript. Hernan Valdez and Gene Wallenstein, employees of Pfizer Inc, provided intellectual input during the manuscript development. The views and opinions expressed within the manuscript are those of all authors and do not necessarily represent those of the funding organization. All authors had full access to all of the data in this study and take complete responsibility for the integrity of the data and accuracy of the data analysis. AWA, JWK, SR, CM, HT, and MK were involved in the conception and design of the work. JWK and SR were involved in data acquisition and analyses. All authors were involved in data interpretation and manuscript drafting, reviewing, and development. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval to the version to be published. Medical writing support, under the direction of the authors, was provided by Neil Cockburn of Complete Medical Communications and was funded by Pfizer Inc. Joaquim Nascimento of Vanguard Strategy provided intellectual input during the manuscript development. Data from this work were presented at meetings of the American Academy of Dermatology-Winter 2015, Dermatology Nurses' Association 2015, and National Psoriasis Foundation 2015.

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Pfizer Inc. CM is an employee and shareholder of Pfizer Inc. HT is an employee and shareholder of Pfizer Inc. MK is an employee and shareholder of Pfizer Inc.

**Compliance with Ethics Guidelines.** This was a retrospective study using Health Insurance Portability and Accountability Act compliant health-plan claims data, exempt from Institutional Review Board requirements.

**Data Availability.** The datasets during and/or analyzed in the current study are available from the corresponding author on reasonable request.

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