Psoriasis: Targets and Therapy

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ORIGINAL RESEARCH

Evolution of Drug Supply for Psoriasis from 2010 to 2022 – Real-World Claims Data Analysis in Germany

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Purpose: The management of psoriasis has undergone substantial evolution; however, the long-term prescription trends remain ambiguous. This study utilised a comprehensive data set of psoriasis drug prescriptions in Germany from 2010 to 2022, with the objective of evaluating the evolution of treatment modalities over time.

Methods: A retrospective longitudinal claims data analysis on systemic biologicals, non-biologicals, and topical treatments for psoriasis was conducted covering prescription rates, medical costs from the payer's perspective, and defined daily doses (DDDs).

Results: Psoriasis prevalence increased slightly from 2.6% in 2010 to 2.7% in 2022. During this period, the proportion of persons receiving prescriptions rose from 55.0% in 2010 to 57.4% in 2022. By 2022, 46.2% of these persons received topical treatments, 13.0% systemic glucocorticosteroids (SCS), 6.7% non-biologicals, and 6.2% biologicals. Compared to 2010, the use of biologicals increased by 449.8%, SCS by 12.6%, non-biologicals by 13.9%, while topical treatments decreased by 3.2%. The annual cost per person treated with a biologic decreased from €16,315 to €13,412, while non-biologic and topical therapy costs increased slightly. Adalimumab was the most frequently prescribed systemic drug, followed by ustekinumab and secukinumab. The highest mean costs per-person were for ustekinumab (€19,717) and risankizumab (€16,986).

Conclusion: In more than a decade, the use of innovative systemic drugs, especially biologicals, in Germany has increased substantially. Despite their high cost, biologic expenses per person have slightly decreased over time.

Keywords: statutory health insurance, claims data, treatment, prescription

Introduction

Psoriasis is a chronic systemic inflammatory disease characterised by chronic skin lesions, a high level of comorbidity and considerable distress leading to marked losses of health-related quality of life.[1] This affects both physical and psychological well-being, as well as social relationships and the ability to function in everyday life.[1] Psoriasis is also associated with a significant socio-economic burden.[2] The high annual average costs-of-illness per patient of €5500 are mainly related to medication.[2,3] In 2014, the World Health Organization (WHO) declared psoriasis to be one of the five non-infectious diseases of particular public health importance and confirmed this in the Global Report on Psoriasis 2016.[4]

The choice of psoriasis treatment depends on the individual patient's clinical phenotype and severity, subjective level of suffering, preferences and treatment goals, as well as comorbidities. Previous treatment responses also impact clinical decisions.[5–8] The range of effective systemic biologic therapies has grown steadily in recent years and by 2024 a total of 25 single compounds has been approved for the systemic treatment of psoriasis in Europe. However, to the best of our knowledge, there is no comprehensive evaluation of how the supply of psoriasis drugs has developed over time in Germany.

Routine claims data from the German Statutory Health Insurances (SHI) system can support the understanding health care services, patterns of care, quality of care, resource use and costs.[9] This study aims to fill this gap by analyzing the evolution of psoriasis drug supply in Germany from 2010 to 2022, using real-world claims data.

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Specifically, we address the following research questions:

1. How has the prescription of psoriasis medications and the annual average cost per person changed over time?
2. What are the trends in the use of biologicals versus traditional systemic or topical therapies?

Materials and Methods

Study Design and Data Source

This retrospective longitudinal health care study analysed an anonymised 40%-sample of all members of a large, nationwide health insurance company, DAK-Gesundheit (2020, N=2,885,984; 56.8% women, average age 48.6 years).

Study Population and Drug Supply

The prevalent insured individuals in Germany (aged ≥ 18 years) diagnosed with psoriasis were identified utilizing the ICD-10 GM classification (L40.0–0.4; L40.7–0.9). In accordance with previous methodological work, individuals were included in the study if they had at least one specific inpatient main diagnosis or at least one confirmed outpatient psoriasis diagnosis within the respective observation year.[10] In addition, individuals had to be insured for at least one day per quarter during the respective year. Consequently, persons were excluded if they were not continuously insured, had died, had not been diagnosed with psoriasis, or were younger than 18 years in the respective observation year. Furthermore, individuals afflicted with psoriatic arthritis were excluded on the basis of divergent therapeutic interventions.

All outpatient drug prescriptions (via the Anatomical Therapeutic Chemical (ATC) classification system) relevant to the treatment of psoriasis were identified (Table S1). This encompasses systemic biologicals, systemic non-biologicals, as well as topical therapeutics and phototherapy. Additionally, psoriasis-related treatments with phototherapy (selective phototherapy (fee schedule items - 30,430), UV therapy (PUVA), balneophototherapy (fee schedule items - 30,431, 10,350)) were analysed across all years.

Statistics

Prevalence rates are reported as percentages with their corresponding 95% confidence intervals (CI) and standardised according to the German National Statistics Agency Destatis as of 31 December of the respective year (direct standardisation). Age, sex and all hospitalisations for psoriasis (principal diagnosis) were considered as baseline characteristics of the study population. The numerator for the estimation comprised the count of insured individuals, while the denominator encompassed all insured individuals within the sample. In addition to frequency of treatment, the total cumulative defined daily dose (DDD) was also analysed. DDDs are used for international comparisons of drug use and do not necessarily reflect the therapeutically appropriate dose. We calculated the average annual direct drug costs per person and examined changes in these costs over the study period. We used GGbreaks to visualise broken axes.[11] Statistical analyses were conducted using SAS version 9.4 German (SAS Institute, Cary, North Carolina 27513–2414, USA).

Results

Study Population

From 2010 to 2022 the standardised prevalence of psoriasis increased from 2.6% (CI 2.6–2.7) to 2.7% (CI 2.7). Mean age of persons with psoriasis was 62 years (±16.8), 60.0% were female. There was a decrease in inpatient stays from 0.8% (CI 0.7–0.9) in 2017 to 0.5% (CI 0.5–0.6) in 2022.

Drug Prescriptions and Costs

In 2022, 57.4% of persons coded with psoriasis received a prescription (55.0% in 2010). In 2022 46.2% of persons with psoriasis received topical treatments and 25.9% systemics. 13.0% received systemic glucocorticosteroids (SCS), 6.7% non-biologicals and 6.2% biologicals (Figure 1). In the observation period the share of topical treatments decreased by

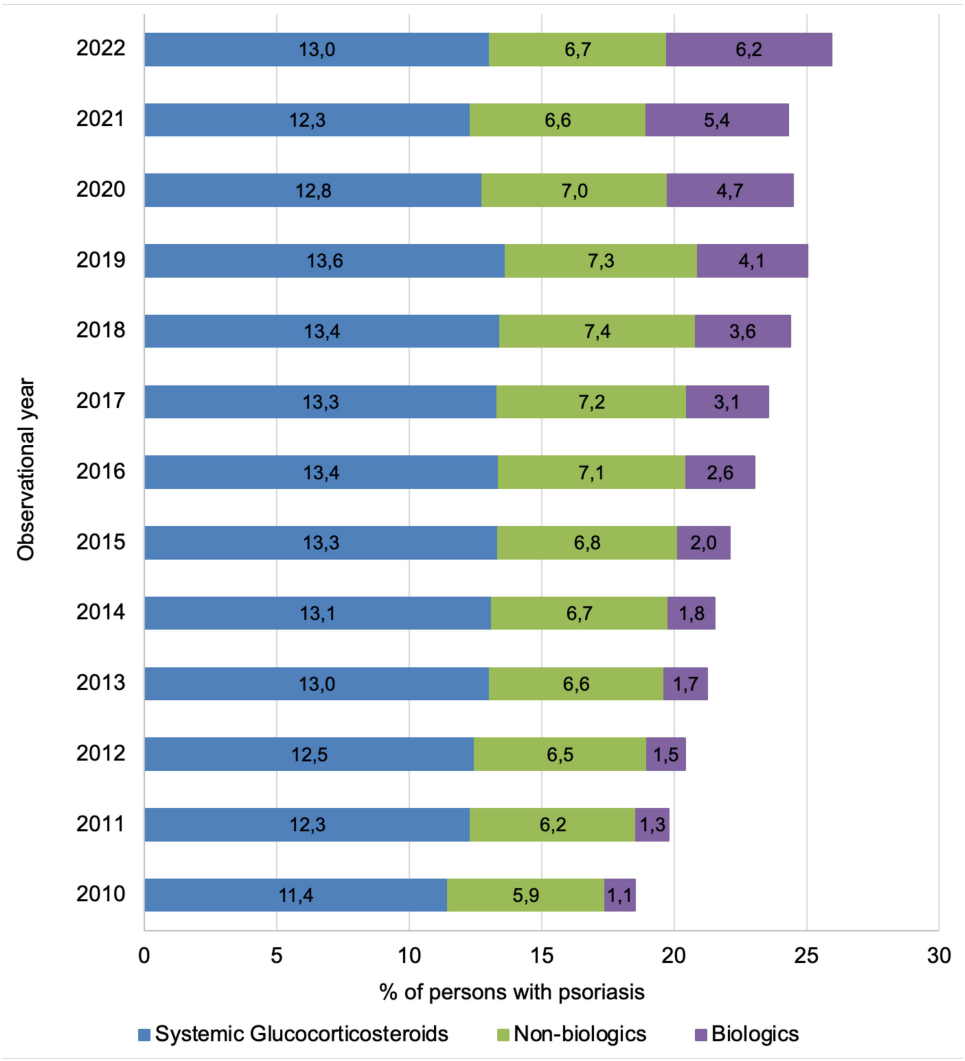

Figure 1 Systemic drug use among persons with psoriasis in Germany receiving at least one drug prescription per year from 2010 to 2022 (multiple counting possible).

3.2% (from 47.7 to 46,2%), while the share of biologicals increased by 449.8% (from 1,1% to 6.2%) and the share of non-biologicals and SCS increased by 12.6% (from 5,9% to 6,7%) and 13.9% (from 11.4% to 13.0%) respectively.

The total DDD of antipsoriatic drugs steadily increased from 2010 to 2022 for all drug groups (biologicals: 5,454,301 DDD to 36,111,422 DDD; non-biologicals: 39,987,371 to 52,436,686 DDD; topicals: 88,090,551 DDD to 113,482,617 DDD). In contrast, the mean costs per person for biologicals decreased from €16,315 in 2010 to €13,412 in 2020, while it increased from €310 to €505 for non- biologicals and from €82 to €108 for topical drugs (total costs from €63,442 to €89,527).

TCS were the most frequently prescribed topical drugs, with 78.0% of all persons having prescription drugs receiving at least one prescription (49.0% class III, 21.4% combinations, 17.7% class IV and 8.5% class I to II), followed by Vitamin D3 analogues and fixed combinations of Vitamin D3 analogues and steroids with 42.7% (Figures 2 and 3). The mean costs per person and the total DDD of TCS changed only slightly from 2010 to 2022. (€45 to €47; 52,414,541 to 63,632,678 DDD). Of the topical treatment Vitamin D3 analogues and their combinations were by far the most expensive drugs of all nine included topicals, with an increasing mean cost per person of €176 (Vitamin D3) in 2022.

Of the eight non-biological systemic drugs analysed, SCS were by far the most frequently prescribed drugs (72.5%), followed by Methotrexate (28.9%) and fumaric acid esters (FAE). The latter were the most expensive non-biological drugs until 2014, with mean costs per person of €1668 in 2020. Its costs remained constant until 2020, despite a reduction in the

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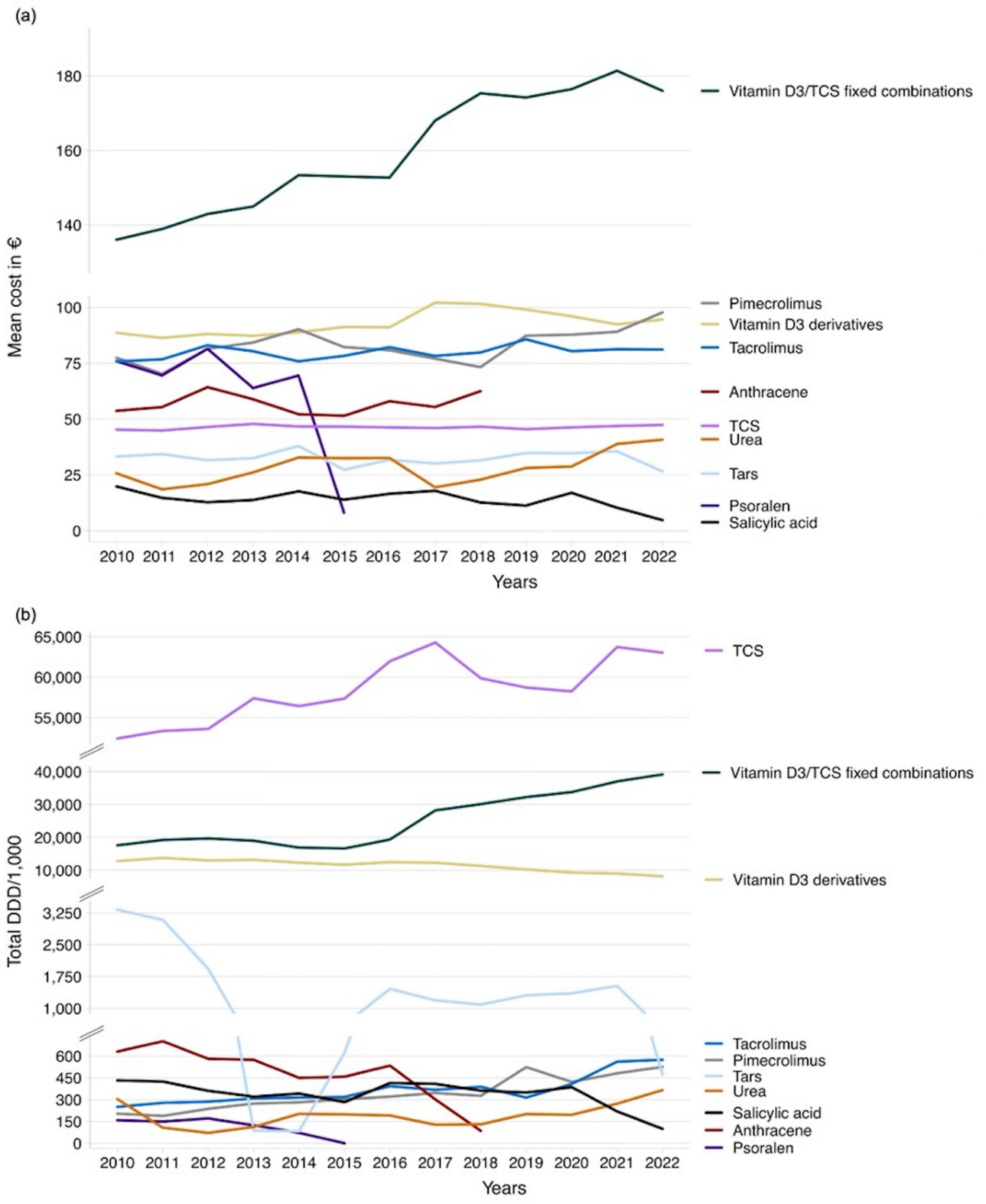

Figure 2 Annual mean costs per person (€) (**a**) and total defined daily doses (DDD), (**b**) of topical therapeutics for psoriasis in Germany between 2010 and 2022.
Abbreviation: TCS, topical glucocorticosteroids.

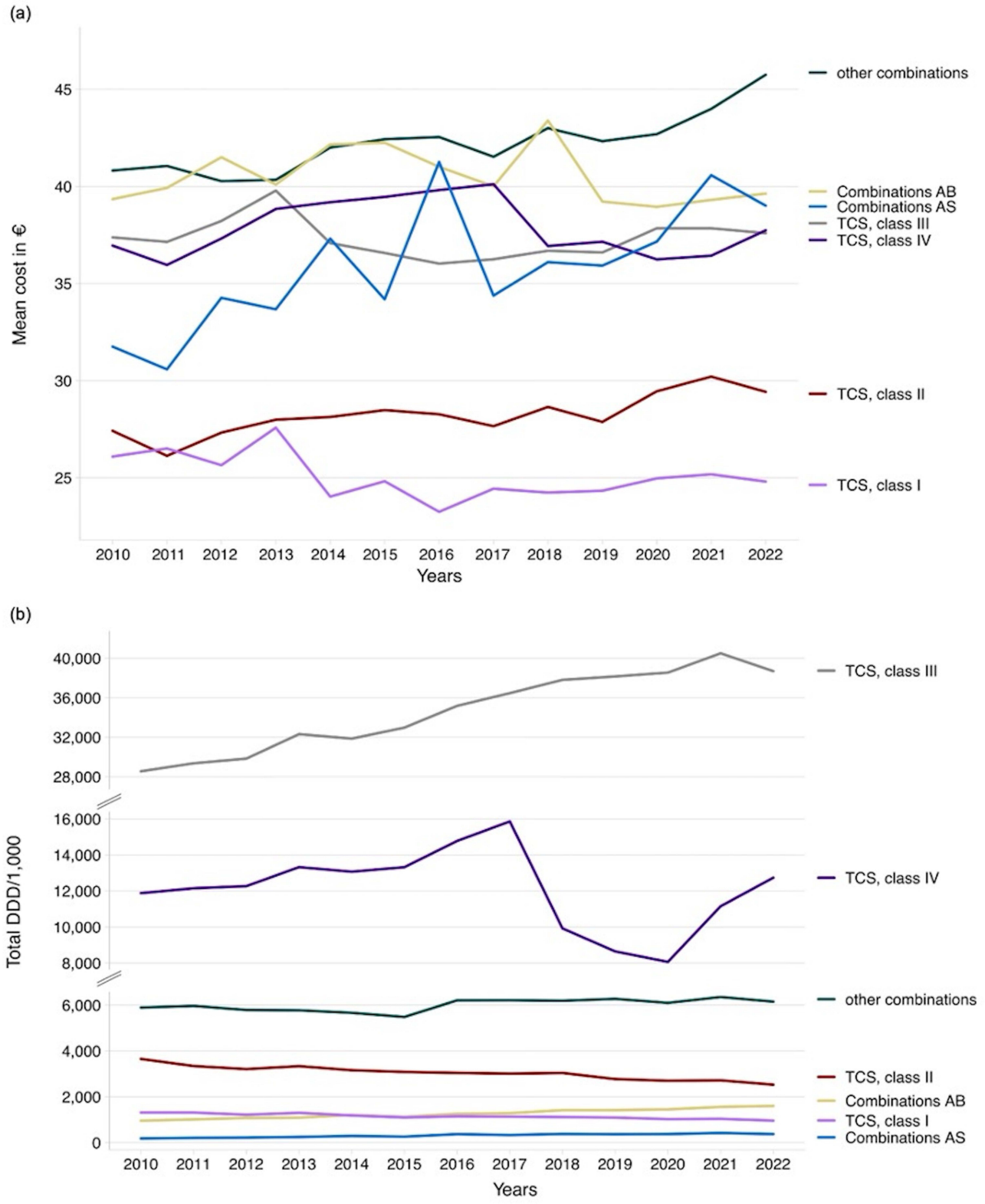

Figure 3 Annual mean costs per person (€) (**a**) and total defined daily doses (DDD), (**b**) of topical glucocorticosteroids (TCS) for psoriasis in Germany between 2010 and 2022.
Abbreviations: TCS, topical glucocorticosteroids; Combinations AS, TCS with antiseptics; Combinations AB, TCS with antibiotics.

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prescribed DDDs. Apremilast was prescribed from 2015 with 234,321 DDD and mean costs per person of €5572, and rose just one year later to 1,624,097 DDD and mean costs per person of €7995, which decreased to €6837 in 2022 (Figure 4).

By 2014, five biologicals were approved for the treatment of psoriasis (ustekinumab, adalimumab, etanercept, infliximab and certolizumab pegol (since 2018, previously only for psoriatic arthritis). A further six biologicals were approved until 2022 (secukinumab, ixekizumab, guselkumab, brodalumab, risankizumab, tildrakizumab; Figure 5). In 2022, the total prescription volume for systemic antipsoriatic drugs was 36,111,422 DDD, with adalimumab being the most frequently prescribed drug (25.0%; 6,949,914 DDD), followed by secukinumab (18.7%; 5,869,206 DDD), ustekinumab (9.7%; 5,194,895 DDD) and risankizumab (6.7%; 2,325,396 DDD). Ustekinumab (mean annual costs per person treated €19,718), risankizumab (€16,986) and secukinumab (€14,475) induced the highest average annual costs per person treated. Despite an increase in the volume of prescriptions for all biologicals, the annual mean costs per person with psoriasis decreased for adalimumab (€8472), etanercept (€8279), infliximab (€9553), ixekizumab (€12,756) and tildrakizumab (€11,597).

Phototherapy

Overall, the proportion of persons with psoriasis who received phototherapy decreased over the years from 4.1% in 2010 to 2.1% in 2022 (Figure S1). Men were more likely to receive phototherapy in all years (2.2% vs 2.0% in women in 2022), and the average age was 58 years. The proportion of individuals with psoriasis and selective phototherapy declined over the years under observation (2022, 1.0%; 0.3%). Persons who received balneophototherapy were slightly younger than those who received selective phototherapy or PUVA (Mean age 56 years ±16.5 versus 59 years ±16.5 and 59 years ±15.9, respectively).

Discussion

With this large-scale claims data analysis robust insights into long-term development of antipsoriatic therapies used in Germany were obtained.

Given the changing landscape of treatment with ever more systemic innovations getting into health care, the take-up of the innovations and the overall situation of health care for psoriasis is of utmost interest. A special focus needs to be the accordance of treatments with the S3 guideline. Following this, topical therapy is typically initiated for persons with mild psoriasis, with consideration given to the specific location and condition of the affected skin. TCS monotherapies were the most frequently utilized topical medication, followed by vitamin D3 analogues and their fixed combinations with TCS. The claims data analysed do not contain detailed clinical information, such as the skin condition, and this cannot control for the correct single clinical indication. However, the total use of drugs observed in the claims data can well be considered as an indicator for guideline compliance on a large scale: In the topical area, the distribution of drugs aligns with the treatment recommendations from the guidelines[7,8,12–14] as the most commonly used TCS were class III and IV compounds, as well as combinations with calcipotriol. The guidelines recommend the use of TCS with a high therapeutic index and thus a favourable risk-benefit ratio. This is only partly given and needs further improvements. Other concomitant basic therapies without active medication, which include urea and salicylic acid as active ingredients in addition to ointment bases, could not completely be analysed since they are largely paid by the patients and are not covered by health insurance. In case of an inadequate response to topical therapy or the presence of moderate to severe psoriasis, systemic antipsoriatic drugs are recommended. Although explicitly not recommended by the guidelines, systemic glucocorticosteroids (SCS) were the most frequently prescribed systemics, followed by methotrexate. The consistently high use of SCS has already been described as a problem in Germany in 2011.[15] It neither corresponds with the evidence-based recommendations from the German S3-guideline nor with the availability of a large number of approved non-biological systemic drugs.[5–8] Remarkably, most of the SCS prescriptions do not derive from dermatologists who are obviously more familiar with the guideline.[16] After controlling for comorbidity which may require systemic steroids such as autoimmune diseases, the overuse of SCS still persisted, indicating that it is not raised by medical reasons. Thus, the problem of SCS overuse needs to be addressed in the near future since SCS steroid use beyond short term has been shown to be explicitly harmful in several chronic diseases.[17,18] The greatest increase in use of an approved antipsoriatic drug was observed following the invention of dimethyl fumarate (DMF) in 2017, which is comparable in effectiveness to fumaric acid esters but more cost-effective. The utilisation of ciclosporin and fumaric acids exhibited a slight decrease. This aligns with the prevailing recommendations, which stipulate that ciclosporin is not preferred for long-term therapy due to its considerable risks of side effects.[5–8]

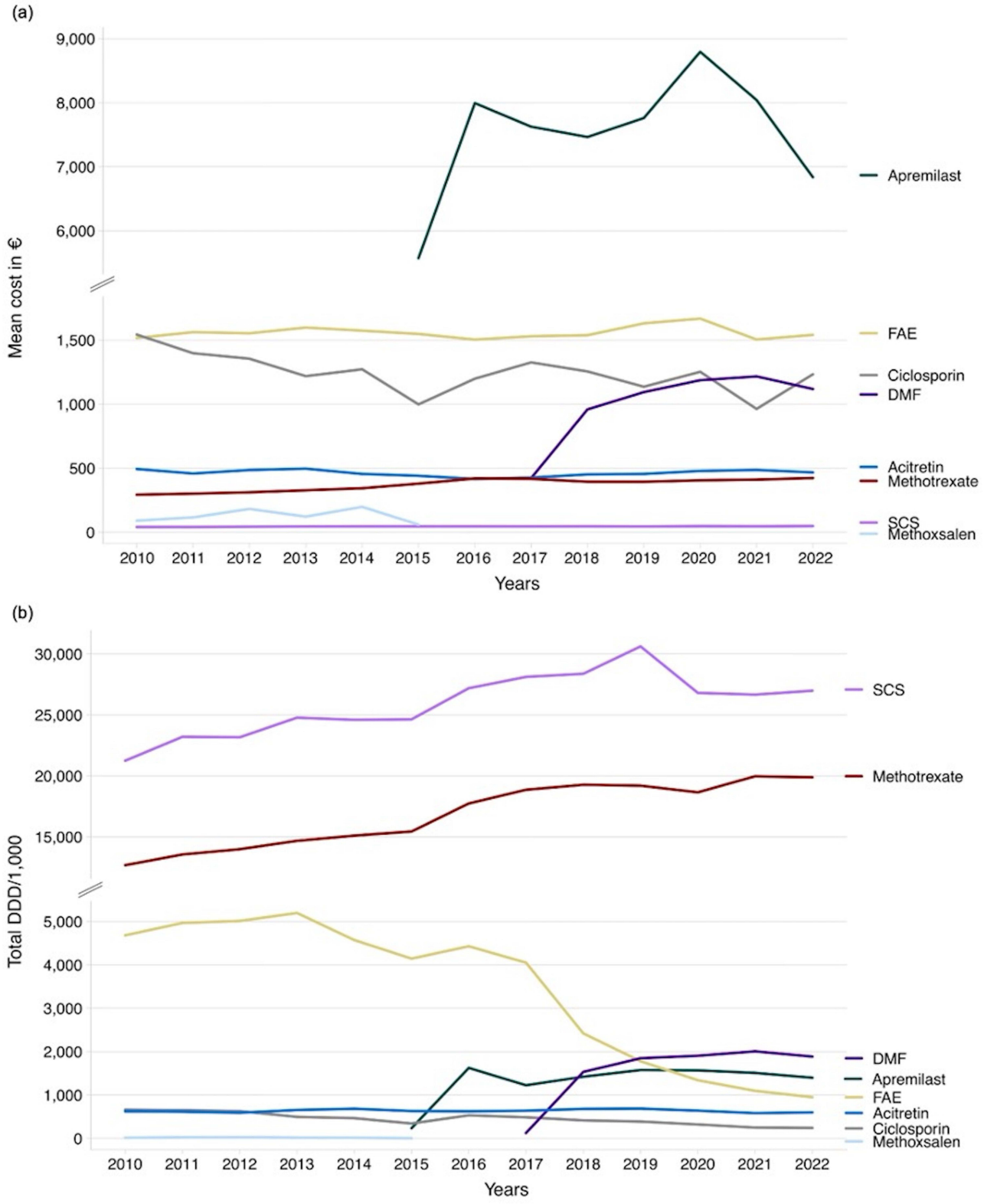

Figure 4 Annual mean costs per person (€) (**a**) and total defined daily doses (DDD), (**b**) of non-biological systemic drugs for psoriasis in Germany between 2010 and 2022.
Abbreviations: SCS, systemic glucocorticosteroids; DMF, Dimethyl fumarate; FAE, Fumaric acid esters.

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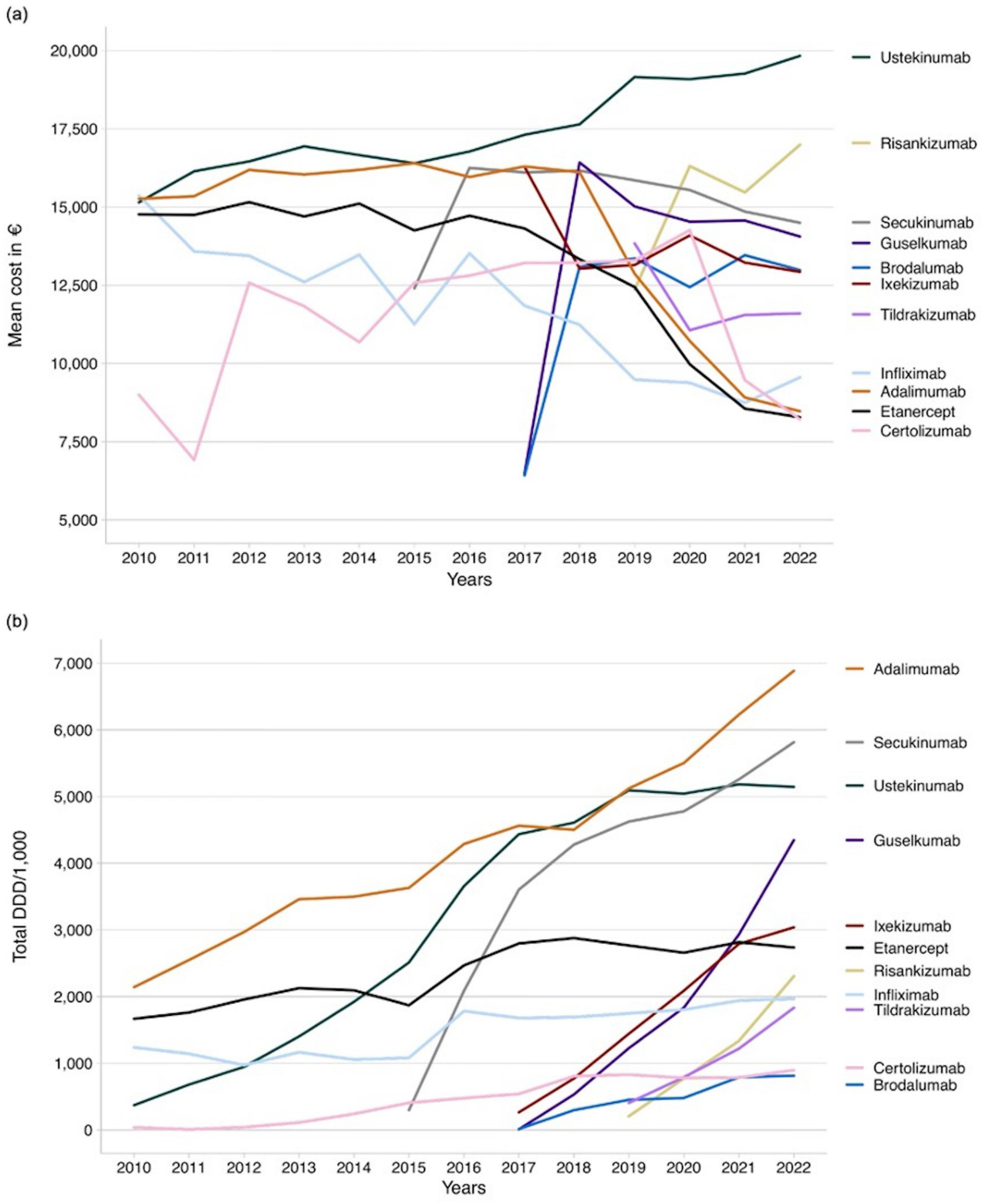

Figure 5 Annual mean costs per person (€) (**a**) and total defined daily doses (DDD), (**b**) of biological systemic drugs for psoriasis in Germany between 2010 and 2022.

In spite of the frequent use of SCS, the use of approved systemic antipsoriatic drugs has markedly increased in Germany, reflecting the willingness to use the growing number of innovations for psoriasis as recommended by the guideline. This rise may also explain the decline in phototherapy to 2.1%. Phototherapy may be contraindicated in some patients and considered too burdensome for others since it requires many visits to the dermatologist which most patients cannot organize.

The study data indicate a higher therapeutic effect of biological versus non- biological systemic drugs, suggesting their first line-use in severe disease.[19] On the one hand, the use of biologicals results in a significant increase in pharmaceutical expenses. However, the use of these drugs can also result in reduction of the costs associated with higher inflammatory activity resulting in inpatient stays or prolonged treatment of severe disease.[20] Accordingly, a previous study demonstrated a notable enhancement in both clinical (severity) and patient-reported (quality of life and treatment benefit) parameters in patients treated with biologicals.[21] In light of the markedly superior effectiveness of contemporary biologicals, the additional costs of the drugs were more than compensated for by the benefits generated in current economic modelling. Additionally, the highly effective modern drugs were found to be more economical.[22,23] The utilisation of biosimilars within active ingredient groups may facilitate the achievement of future savings.

These biosimilars have a comparable efficacy and safety profile and therefore may offer a more favourable cost-benefit ratio– as long as the originators do not follow with price reductions.[24,25] However, a potential loss of efficacy when switching to a biosimilar has been demonstrated in individuals with hidradenitis.[26] Consequently, further studies are required to confirm these findings in persons with psoriasis. Nevertheless, the cost factor should not be the sole consideration when selecting a drug, in order to avoid limiting the clinical discretion of practitioners.[27,28]

Strengths and Limitations

A strength of this analysis is the large volume of claims data and their scientific added value. The external validity of the data – in terms of population coverage – is high since around 90% of the German population is covered by a statutory health insurance.[9] Data- and method-based limitations must nevertheless be taken into account when interpreting the results. For example, we presented data on people insured through a public system and therefore cannot make statements about those approximately 10% privately insured. In general, populations of different SHI may differ.[29] To keep these differences as small as possible, prevalence and incidence rates were adjusted to the total German population by age and gender. Furthermore, a study on psoriasis showed that the epidemiological results of the DAK-G can be extrapolated without restriction to the SHI population if they are standardised by age and sex.[10] A large proportion of persons with psoriasis were treated with topical prescription drugs. In addition, topical over-the-counter drugs may have been used, such as preparations containing urea or salicylic acid which cannot be represented by SHI data. Although this underestimates the total costs-of-illness, the cost from the payer perspective chosen for the current analysis are not affected. Furthermore, important aspects of drug therapy, such as the assessment of patient goals and benefits, quality of life, and the individualisation of treatment goals, cannot be evaluated with the currently available data.

Conclusion

The data analysis for the period from 2010 to 2022 indicates that the proportion of persons with psoriasis treated with biologicals is increasing. The continued high utilisation of systemic glucocorticosteroids must be viewed with a degree of scepticism in the context of the broader provision of systemic therapeutics. Given the growing variety of approved medications and the continuous expansion of biologicals, differentiation of therapies according to patient preferences, psychosocial measures, education, rehabilitation measures and lifestyle changes is becoming increasingly important in health care for psoriasis.

Abbreviations

ATC, Anatomical Therapeutic Chemical; CI, Confidence intervals; DAK, Health insurance company in Germany; DDD, Defined daily doses; DMF, Dimethyl fumarate; FAE, Fumaric acid esters; SCS, Systemic glucocorticosteroids; SHI, Statutory Health Insurances; TCS, Topical glucocorticosteroids; WHO, World Health Organization; PUVA, UV therapy.

Data Sharing Statement

The datasets generated for the claims data cohort are not available, as the use of claims data is restricted to authorized researchers.

Ethics Approval

The study was conducted according to national guidelines for the use of administrative databases (Swart, 2014; Arbeitsgruppe Epidemiologische Methoden der Deutschen Arbeitsgemeinschaft für Epidemiologie, 2004). According to those guidelines, no approval of an ethical committee is required.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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