Dermatol Ther (Heidelb) (2023) 13:581–594
https://doi.org/10.1007/s13555-022-00872-1

ORIGINAL RESEARCH

Real-World Findings on the Characteristics and Treatment Exposures of Patients with Hidradenitis Suppurativa from US Claims Data

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Received: October 11, 2022 / Accepted: December 1, 2022 / Published online: December 31, 2022

ABSTRACT

Introduction: Hidradenitis suppurativa (HS) is a chronic, debilitating, and painful inflammatory skin disease that significantly and negatively impacts patients' quality of life. The prevalence of HS in the USA is estimated to be 0.10%, with worldwide reports suggesting a prevalence closer to 1%. There is limited real-world evidence available on the care of patients with HS. We aimed to evaluate the trends in clinical care and treatment in the patient population with HS in the USA in a real-world setting.

Methods: A cohort study was conducted using claims data from IBM MarketScan Databases, including the US Commercial Claims and Encounters with Medicare Supplemental and Coordination of Benefits (CCAE+MDCR) database and IBM US Medicaid database.

Results: The annual prevalence of HS increased from 0.06% (2008) to 0.14% (2017), and from 0.17% (2008) to 0.31% (2017) among CCAE+MDCR and Medicaid patients, respectively. Dermatologist visits increased from 31.9% (2008) to 47.8% (2019) in CCAE+MDCR

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patients, and decreased from 10.9% (2008) to 8.5% (2018) in Medicaid patients. Opioid use decreased from 45.4% (2008) to 25.5% (2019) among CCAE+MDCR patients, and from 71.3% (2008) to 48.1% (2018) among Medicaid patients. Only 8.4% of CCAE+MDCR patients and 5.8% of Medicaid patients were exposed to any biologic in 2018.

Conclusions: Improved care and treatment of HS over the last decade, including the emergence of new treatments, have been accompanied by an increase in awareness and reported prevalence of the disease. However, there are still gaps in access to dermatologic care and low utilization of biologic therapies among patients with HS.

Keywords: Biologic; Dermatologist; Hidradenitis suppurativa; Prevalence; Real-world; United States

Key Summary Points

Why Carry Out This Study?

The documented prevalence of hidradenitis suppurativa (HS) in the USA has increased over the last decade, likely due to increased awareness of the disease and increased referrals to dermatologists.

However, there is limited real-world evidence available on the treatment and care of patients with HS.

This study aimed to explore trends in the clinical care of patients with HS in the USA over the last decade to inform and optimize patient care.

What was learned from the study?

Access to dermatologists and biologic treatments among both commercially and federally insured patients is still low overall, and disparities in HS care exist between insurance types.

Increasing dermatologist access among patients with HS is likely to improve patient care and outcomes.

DIGITAL FEATURES

This article is published with digital features, including an infographic to facilitate understanding of the article. To view digital features for this article go to https://doi.org/10.6084/m9.figshare.21656852.

INTRODUCTION

Hidradenitis suppurativa (HS) is a debilitating, chronic, inflammatory skin disease of the hair follicle that causes recurrent, painful, and inflamed nodules, abscesses, and tunnels that lead to scarring, and is frequently associated with drainage and foul odor [1–4]. The prevalence of HS is estimated to be approximately 0.10% in the USA [5], and the standardized prevalence of HS has been reported to be highest among women (0.14%), patients aged 30–39 years (0.17%), and African Americans (0.30%) [5]. In actuality, the reported prevalence of HS in the USA may be an underestimation as a consequence of high rates of underdiagnosis and misdiagnosis, since prevalence has been found to be as high as 1% in Europe [6].

HS has a profound negative impact on patients and their quality of life due to disabling symptoms such as pain, scarring, and disfigurement [7–10]. The disease is often recognized late with delayed diagnosis, inappropriate or ineffective disease management, and unpredictable disease progression [11, 12]. The debilitating nature of the disease can be attributed to the pain caused by skin lesions, with higher pain scores than many other skin diseases [13, 14], as well as functional limitations due to permanent scarring resulting from severe longstanding HS [3]. The negative effects on patients' quality of life can often result in social withdrawal, unemployment, depression, and suicidal thoughts [15]. Multiple comorbidities also have known associations with HS, including obesity, anxiety, depression, diabetes, polycystic ovarian syndrome, inflammatory bowel disease, spondyloarthritis, cardiovascular

disease, and other inflammatory diseases [16–19].

Most of the currently available treatments for HS are directed toward managing the lesions and disease symptoms, and the most common therapies consist of antibiotics with anti-inflammatory properties, such as tetracyclines, clindamycin, and rifampin, and other anti-inflammatory drugs, including dapsone, fumarates, or cyclosporine, as well as retinoids, pain medication, and surgical procedures [20, 21]. Adalimumab was approved in the USA in September 2015 and is currently the only biologic that has received approval for the treatment of moderate-to-severe HS in adults, as well as adolescents aged 12 years and older [22], although other biologics such as infliximab are used off-label [23].

There is limited real-world evidence available in the literature on the treatment exposures and care of patients with HS. The Global Survey Of Impact and Healthcare Needs (Global VOICE) study is one of the few real-world studies to have evaluated HS diagnosis, care, pain, flares, comorbidities, treatment satisfaction, and life impact. However, this cross-sectional study was limited to self-reported care experiences and may have overrepresented patients having severe disease [24].

This study aimed to describe the patient population with HS in the USA and their care in the last decade, which may help inform and optimize HS care in routine clinical practice. The study objectives were to estimate the prevalence of HS annually (2008–2017), to describe the treatment exposures among patients with HS by year (2008–2019), and to describe treatment progression among patients with HS (2016–2017).

METHODS

Study Design

The study described herein was a cohort study conducted using IBM MarketScan Databases: US Commercial Claims and Encounters with Medicare Supplemental and Coordination of Benefits (CCAE+MDCR) databases, and IBM US Medicaid database. The databases include enrollment history and claims from both medical (inpatient, outpatient, and emergency care) and pharmacy services for privately and publicly insured people in the USA. The CCAE+MDCR database includes patients with privately funded health insurance, while the Medicaid database comprises patients who receive publicly funded health insurance.

The CCAE data include individual medical and drug insurance claims; the claims are acquired from employers and health plans that provide insurance coverage for employees and their dependents. MDCR covers Medicare-eligible retirees with employer-sponsored Medicare supplemental insurance. The Medicaid database contains records of inpatient and outpatient services, inpatient admissions, and prescription drug claims for Medicaid beneficiaries from multiple states. Between the different insurance types, all enrolled patients do not receive equal coverage, and insurance benefits vary widely between companies and plans, such that patients may need to pay out-of-pocket for some treatments.

Annual cohorts of patients with HS in the USA (2008–2019) were identified to evaluate the prevalence of HS over time in the CCAE+MDCR and Medicaid databases. HS cohorts of US patients (2016–2018) were also identified to evaluate the treatment exposures of CCAE+MDCR and Medicaid patients with HS.

Ethics committee approval was not required as this study utilized deidentified claims data. The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Consent from patients for the use of their data in the study and its publication was also not required as this was a retrospective cohort study that used deidentified claims data.

Participants

Patients included within the annual cohorts were ≥18 years of age with ≥1 HS medical claim [International Classification of Diseases (ICD)-9/ICD-10] by any physician type in the specified calendar year and 12 months of continuous enrollment in that calendar year (2008–2019)

[25]. The HS cohorts included patients that were ≥18 years of age with ≥1 HS medical claim (ICD-9/ICD-10) by any physician type on or after 1 January 2016 (first HS claim as index date) and ≥12 months of continuous enrollment preceding and following the HS claim. These two cohorts (annual cohort and HS cohort) were created according to the year of the HS medical claims and can therefore provide distinct insights. The subgroup of the HS cohort that made up patients with ≥1 HS medical claim during the 12 months preceding the index date was termed the "subgroup with an HS claim in the prior year.

$$\text{Prevalence} = \frac{\text{number of prevalent patients in the specified year}}{\text{number of patients with continuous enrollment in the specified year}}$$

Study Variables

Demographic, clinical, and treatment characteristics including gender, age, comorbidities, dermatologist visits, healthcare professional (HCP) types associated with the index HS claim, and treatment history (antibiotics, corticosteroids, pain medications, biologics, drainage/excision procedures) were assessed at baseline. Treatments (antibiotics, corticosteroids, pain medications, biologics, drainage/excision procedures) and the number of HS claims during the 1-year follow-up period following the index date were also assessed.

Statistical Analysis

CCAE+MDCR data and Medicaid data were analyzed separately using descriptive statistics. Continuous data were described using mean, median, standard deviation, minimum, and maximum, while categorical data were described using frequency counts and percentages.

Individuals with continuous insurance enrollment in the specified calendar year served as the denominator for calculations of prevalence estimates and their 95% confidence intervals (CI). Patients with ≥1 claim for HS in the specified year were considered prevalent, such that:

Statistical analyses were conducted using SAS, Version 9.4 (SAS institute, Inc., Cary, NC).

RESULTS

Patient Characteristics

Several cohorts of patients with HS in the USA were identified within the CCAE+MDCR and Medicaid databases: CCAE+MDCR annual cohorts, CCAE+MDCR HS cohorts, CCAE+MDCR HS cohort subgroup with HS claim in the prior year, Medicaid annual cohorts, Medicaid HS cohorts, and Medicaid HS cohort subgroup with HS claim in the prior year.

There were 23,122 patients with HS in the CCAE+MDCR annual cohort in 2019 with an average age of 37.6 years and 78.2% of the cohort being female (Table 1). The CCAE+MDCR HS cohort comprised 34,981 patients, where 75.8% were female and the average age of the cohort was 39.1 years (Table 2). Within the CCAE+MDCR HS cohort, 3036 (8.7%) had ≥1 HS-related medical claim in the year preceding the index date. The most common comorbidities within this subgroup included obesity (24.9%), type II diabetes (14.3%), depression (10.5%), and anxiety (9.4%), where conditions with two or more claims on two separate dates in the year preceding the index date were considered comorbidities (Table 2).

In the Medicaid annual cohort in 2018 there were 10,106 patients with HS, the average age was 34.4 years, and 83.1% were female

Table 1 Annual cohort characteristics

Annual cohort (2008–2019)						
Year	**CCAE+MDCR**			**Medicaid**		
	N	**Mean age, years (SD)**	**Female, %**	***N***	**Mean age, years (SD)**	**Female, %**
2008	13,585	40.5 (13.4)	72.0	1800	33.5 (11.2)	83.9
2009	16,602	40.3 (13.2)	72.6	2724	33.2 (10.9)	85.2
2010	17,179	40.4 (13.5)	73.1	2907	33.0 (10.7)	85.2
2011	20,101	39.7 (13.9)	73.1	3252	32.9 (11.1)	85.1
2012	21,975	39.4 (14.0)	73.0	5870	32.9 (10.5)	86.8
2013	19,616	39.4 (14.1)	73.7	6618	33.5 (10.6)	86.0
2014	21,864	39.2 (13.8)	75.2	8331	33.5 (10.5)	86.0
2015	19,455	39.0 (14.0)	75.5	9522	33.9 (10.7)	85.3
2016	21,031	38.8 (13.9)	75.6	10,913	33.9 (10.7)	84.8
2017	20,899	38.3 (13.5)	77.5	11,594	33.9 (10.8)	84.3
2018	22,522	37.8 (13.0)	77.2	10,106	34.4 (10.9)	83.1
2019	23,122	37.6 (12.9)	78.2	–	–	–

CCAE commercial claims and encounters, *MDCR* Medicare supplemental and coordination of benefits, *SD* standard deviation

(Table 1). The Medicaid HS cohort included 10,420 patients, of whom 84.7% were female and the average age was 34.3 years (Table 2). Among the Medicaid HS cohort, 2296 (22.0%) had ≥1 HS-related medical claim in the year preceding the index date. In this subgroup with an HS claim in the prior year, the most prevalent comorbidities were also obesity (40.9%), depression (26.7%), anxiety (21.9%), and type II diabetes (20.2%) (Table 2).

Annual Prevalence of HS

The annual prevalence of HS increased from 0.06% to 0.14% from 2008 to 2017, respectively, within the CCAE+MDCR database. In the Medicaid database, HS prevalence increased from 0.17% to 0.31% from 2008 to 2017, respectively (Fig. 1a and b).

Visits to HCPs

Within the CCAE+MDCR annual cohorts, the greatest proportion of patients with HS visited dermatologists, while the greatest proportion of patients with HS in the Medicaid annual cohorts visited acute care hospitals (Fig. 2a and b). An increase was also observed in dermatologist and obstetrics & gynecology visits over time among CCAE+MDCR patients (Fig. 2a). Dermatologist visits in the CCAE+MDCR annual cohorts increased from 31.9% to 47.8% between 2008 and 2019, respectively, while in the Medicaid annual cohorts the proportion of patients visiting a dermatologist decreased from 10.9% to 8.5% from 2008 to 2018, respectively (Fig. 2c and d).

Treatment Exposure

Opioid use decreased from 45.4% to 25.5% from 2008 to 2019, respectively, among CCAE+MDCR patients (Fig. 3a) and from 71.3%

Table 2 HS cohort characteristics

HS cohort (2016–2018)							
	N	Mean age, years (SD)	Female, %	Comorbidities[b] (%)			
				Obesity	Type II diabetes	Anxiety	Depression
CCAE+MDCR							
Overall HS cohort	34,981	39.1 (13.7)	75.8	20.7	10.7	10.1	8.6
HS claim in the prior year subgroup[a]	3036	39.6 (13.7)	77.6	24.9	14.3	9.4	10.5
Medicaid							
Overall HS cohort	10,420	34.3 (10.9)	84.7	33.1	16.2	20.0	22.7
HS claim in the prior year subgroup[a]	2296	34.8 (10.6)	83.2	40.9	20.2	21.9	26.7

CCAE commercial claims and encounters, *HS* hidradenitis suppurativa, *MDCR* Medicare supplemental and coordination of benefits, *SD* standard deviation

[a]Patients with ≥1 HS-related medical claim in the year preceding the index date (first HS claim on or after 1 January 2016)

[b]Conditions with ≥2 claims on two separate dates in the year preceding the index date were considered comorbidities and only those represented in >5% of the total HS cohort are shown (excluding the combined 'anxiety and depression' comorbidity among 11.5% of Medicaid patients in the overall HS cohort)

to 48.1% from 2008 to 2018, respectively, among Medicaid patients (Fig. 3b). Only 8.4% of patients in the CCAE+MDCR annual cohort and 5.8% of patients in the Medicaid annual cohort were exposed to any biologic in 2018 (Fig. 3a and b), despite the higher prevalence of HS among Medicaid patients compared with commercially insured patients.

Number of HS Claims and Treatment Exposure in the Follow-Up Period

During the 1-year follow-up period, 29.1% of patients had no HS-related claims and 28.3% had four or more HS claims within the subgroup with an HS claim in the prior year of the CCAE+MDCR HS cohort. Of the Medicaid patients in the HS cohort, 25.0% of patients had no HS-related claims and 35.9% had four or more claims in the 1-year follow-up period within the subgroup with an HS claim in the prior year (Fig. 4a). Among CCAE+MDCR patients, 42.1% had exposure to opioids (excluding tramadol) and 16.3% had exposure to any biologic in the follow-up period. For Medicaid patients, exposure to opioids (excluding tramadol) and exposure to any biologic occurred in 68.0% and 9.7% of patients in the follow-up period, respectively (Fig. 4b).

DISCUSSION

Over the past decade, there have been major shifts in the care and treatment of patients with HS [26], and consistent with our findings, the prevalence of HS appears to be increasing in most databases, though the true prevalence and incidence is still being refined. It has also been suggested that the approval of adalimumab for the treatment of HS in 2015 has led to an increase in awareness of the disease [22]. As such, the overall increase in the prevalence of HS over time observed in both the CCAE+MDCR and Medicaid databases may be

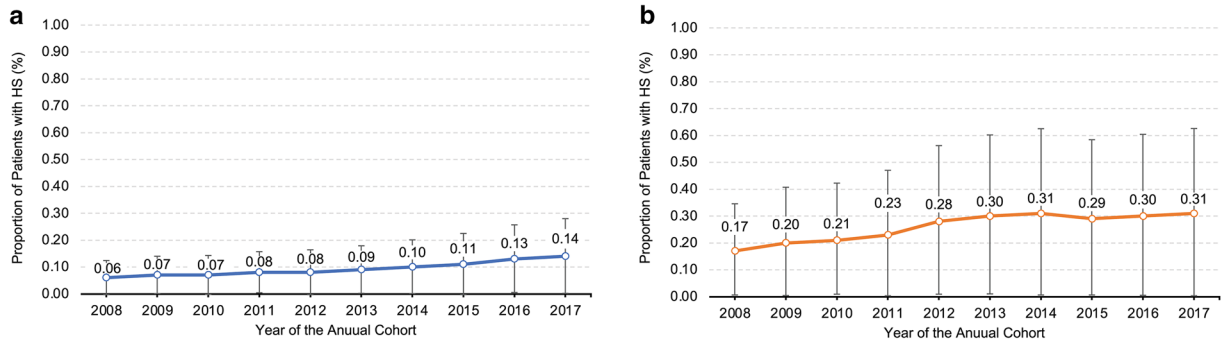

Fig. 1 Annual prevalence of HS. **a** Annual prevalence of HS in the CCAE+MDCR database. **b** Annual prevalence of HS in the Medicaid database. Denominator is all patients ≥18 years of age with 12 months of continuous enrollment in the specified calendar year. *CCAE* commercial claims and encounters, *HS* hidradenitis suppurativa, *MDCR* Medicare supplemental and coordination of benefits

due to increased awareness and increased referrals to dermatologists, rather than an increase in cases of HS. Additionally, the 2016 HS prevalence estimate of 0.13% described in the current study within the CCAE+MDCR database is similar to that of 0.10% reported elsewhere [5], while the 2016 prevalence estimate of 0.30% within the Medicaid database described here is considerably higher than the reported prevalence of 0.10% [5]. However, the CCAE+MDCR and Medicaid 2014 HS prevalence estimates of 0.10% and 0.31%, respectively, are consistent with estimates of 0.098% in Commercial/Medicare patients and 0.301% in Medicaid patients described in another similar claims data study of 11,325 Commercial/Medicare and 5164 Medicaid patients [27]. The HS prevalence described in the current study may still be an underestimation, as claims databases rely on accurate and timely diagnosis of HS. Accurate and timely diagnoses remain a gap in the care of patients with HS, and a mean delay of 10.2 years from symptom onset to diagnosis has been reported [24].

Overall, access to dermatologists is likely suboptimal in both CCAE+MDCR and Medicaid cohorts, especially as a patient may be more likely to receive appropriate and escalating treatments, including biologics, under the care of a dermatologist [28]. This aligns with findings from the Global VOICE study, where a survey of 1299 patients with HS between 2017 and 2018 found that access to dermatology was rated as difficult by 37.0% of patients [24].

Dermatologist visits were more common in CCAE+MDCR patients compared with Medicaid patients. This is compounded by the shifts in HCP visits over time, where increased care by dermatologists was seen in CCAE+MDCR patients over the observed period as compared with Medicaid patients. This reflects a positive shift toward the medical management of HS for CCAE+MDCR patients, as shown by increased dermatology visits and decreased surgery visits over time. Among Medicaid patients, acute care hospital visits were the most common type of HCP visit, and this is consistent with the overall trend of reduced dermatologist management of Medicaid patients compared with CCAE+MDCR patients. Exploring correlations between age/gender, biologic use, and acute care in future research may be useful. Similar disparities in care between commercial and Medicaid patients with HS have been previously reported, suggesting that Medicaid patients experience a particularly high burden of disease and expensive healthcare resource utilization (e.g., high rates of comorbidities, prescription pain medication use, drug discontinuation, emergency department visits, and hospitalization) [27]. Moreover, compared with the 21.8% of patients with HS in the USA reported to have at least one outpatient encounter with a dermatologist over a 3-year period in a retrospective cohort analysis of 42,030 patients [29], the

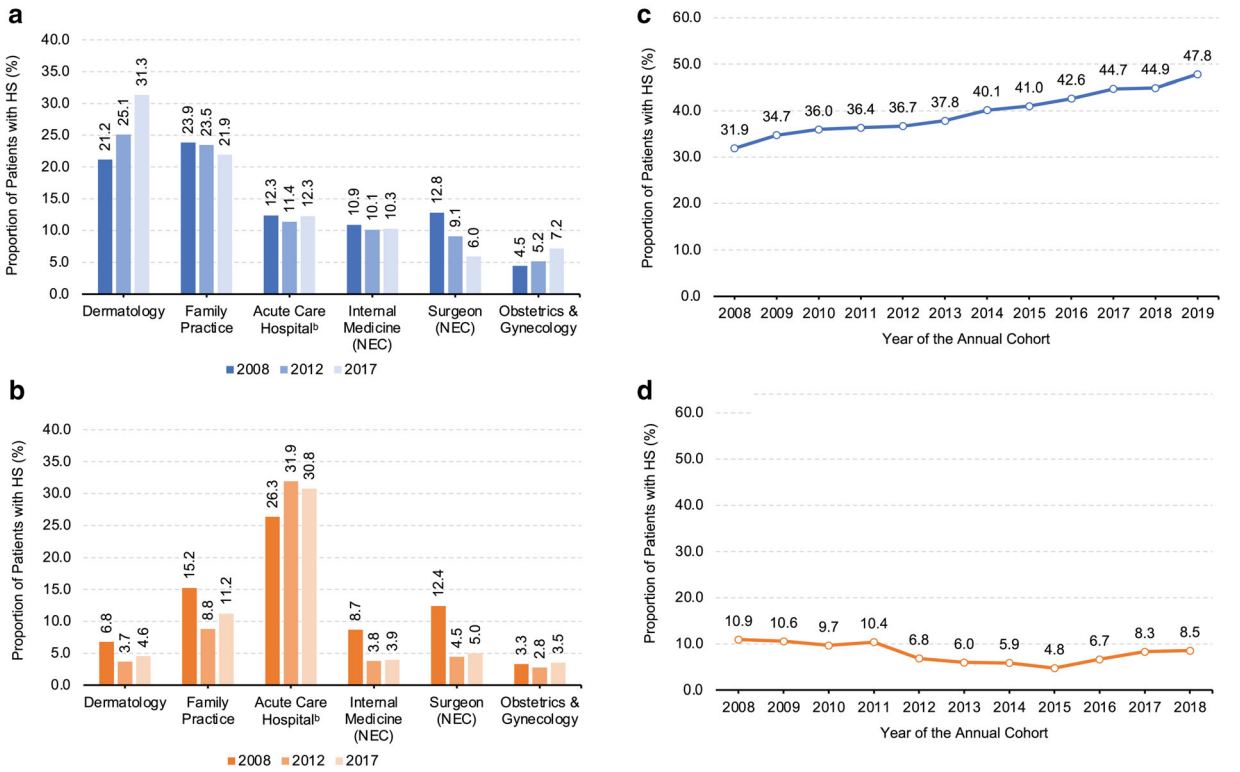

Fig. 2 Visits to HCPs in the annual cohorts. **a** Visits to HCPs for CCAE+MDCR patients. [a]**b** Visits to HCPs for Medicaid patients. [a] **c** Visits to a dermatologist for CCAE+MDCR patients. [c]**d** Visits to a dermatologist for Medicaid patients.[c] [a]Visits to HCP types associated with the HS claim in CCAE+MDCR/Medicaid patients with HS. [b]Acute care hospital includes ER and outpatient urgent care. [c]≥1 dermatology appointments in CCAE+MDCR/Medicaid patients with HS, in that year. *CCAE* commercial claims and encounters, *HCP* healthcare professional, *HS* hidradenitis suppurativa, *MDCR* Medicare supplemental and coordination of benefits, *NEC* not elsewhere classified (used when there is no specific code available to represent the condition)

proportion of patients in the current study who visited a dermatologist was higher within the CCAE+MDCR annual cohort at 47.8% in 2019, and dramatically lower within the Medicaid annual cohort at 8.5% in 2018.

The decrease in opioid use in both CCAE+MDCR and Medicaid patients aligns with the changing patterns of opioid prescriptions in the USA. There have been numerous policy changes and programs aimed at decreasing opioid use [30], as well as some improvements in therapeutic approaches; the relative impact on prescriptions is unknown. Many states have implemented supply-controlling and harm-reduction policy measures, which have resulted in reduced misuse of prescription opioids [31]. In the current study, the proportion of patients with HS exposed to opioids (excluding tramadol) ranged from 45.8%–25.5% between 2008 and 2019 in the CCAE+MDCR annual cohorts, and 73.9–48.1% between 2008 and 2018 within the Medicaid annual cohorts. It is unclear whether opioids were used specifically for HS pain, or other chronic/acute pain. Comparatively, the 1-year incidence of long-term opioid use among opioid-naïve patients with HS in the USA was reported to be 0.33% between 2008 and 2018 in a retrospective cohort study of 22,277 patients [32]. Patients with HS have also been reported to be 1.5 times more likely to have a substance use disorder than patients without HS [33].

The increase in biologic exposure for CCAE+MDCR and Medicaid patients after 2015

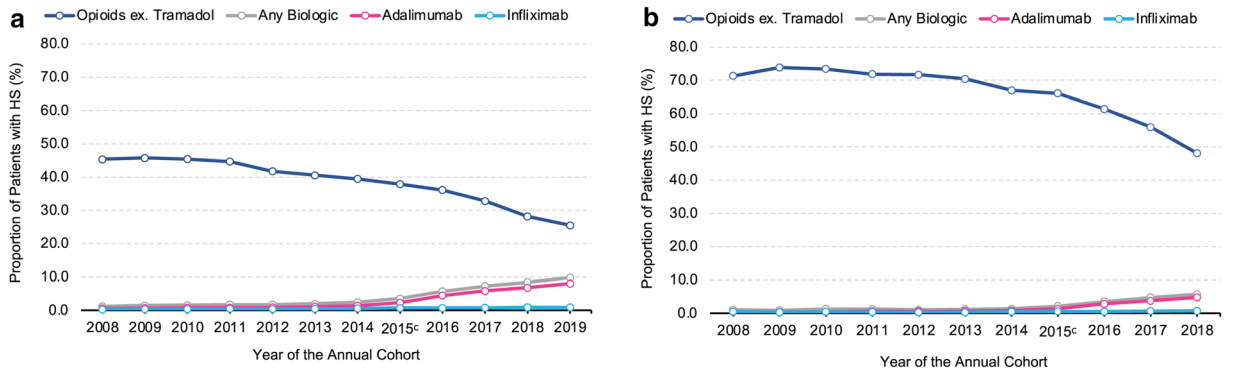

Fig. 3 Treatment exposure in the annual cohorts. **a** Opioid[a] and biologic[b] exposure for CCAE+MDCR patients. **b** Opioid[a] and biologic[b] exposure for Medicaid patients. [a]Patients with ≥1 pharmacy claim for opioids (excluding tramadol) in that year. [b]Patients with ≥1 pharmacy claim for the specified biologic in that year. [c]Adalimumab approved for HS treatment in the USA in 2015. *CCAE* commercial claims and encounters, *ex.* excluding, *HS* hidradenitis suppurativa, *MDCR* Medicare supplemental and coordination of benefits

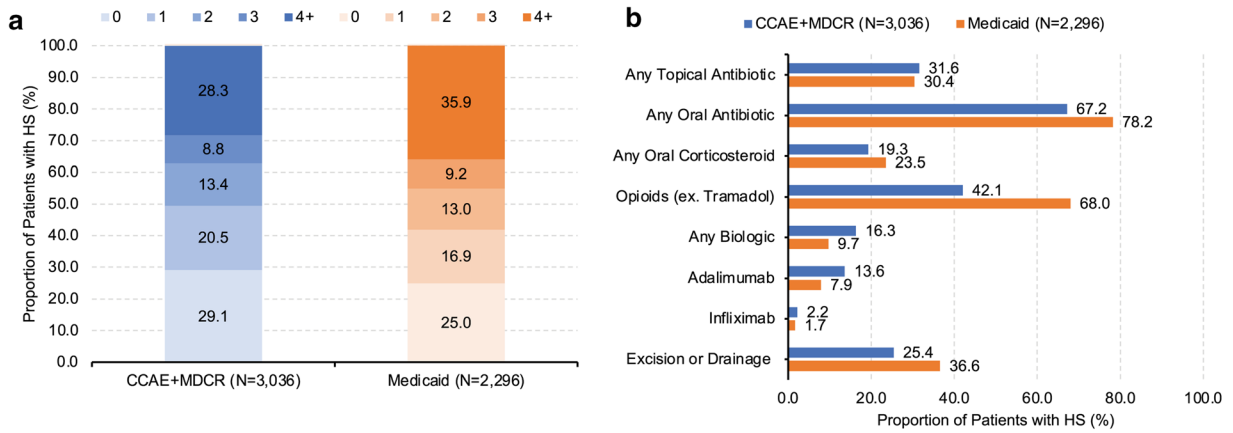

Fig. 4 Number of HS claims[a] and treatment exposure[b] during the 1-year follow-up period. **a** Number of HS claims in the subgroup with an HS claim in the prior year[c] for CCAE+MDCR and Medicaid patients. **b** Treatment exposure in the subgroup with an HS claim in the prior year[c] for CCAE+MDCR and Medicaid patients. [a]HS claims in the 1-year follow-up period, excluding the index claim. [b]≥1 claim for the treatment of interest during the 1-year follow-up period. [c]Patients with ≥1 HS-related medical claim in the year preceding the index date (first HS claim on or after 1 January 2016). *CCAE* commercial claims and encounters, *ex.* excluding, *HS* hidradenitis suppurativa, *MDCR* Medicare supplemental and coordination of benefits

can be attributed to the approval of adalimumab by the Food and Drug Administration (FDA) in the USA in 2015 for the treatment of moderate-to-severe HS [22]. However, biologic exposure is generally low across the commercial CCAE+MDCR and federal Medicaid insurance types. There is lower utilization of adalimumab among federally insured patients compared with commercially insured patients, despite the higher HS prevalence in the Medicaid database. In a cross-sectional analysis of 25,966 patients between 2015 and 2020, 1.8% of patients with HS were reported to have received at least one prescription for adalimumab or infliximab overall, whereas 6.0% of patients with access to dermatology care received one or more

adalimumab/infliximab prescriptions [34]. In comparison, the proportion of patients exposed to adalimumab and infliximab in the current study ranged from 2.3%–8.0% and 0.7%–0.9%, respectively, between 2015 and 2019 in the CCAE+MDCR annual cohorts. In the Medicaid cohorts from 2015 to 2018, between 1.4%–4.8% of patients were exposed to adalimumab and between 0.5%–0.7% were exposed to infliximab. In instances where commercial or federal bodies do not reimburse the cost of the biologics, patients must pay high out-of-pocket costs to cover their treatment or rely on patient assistance programs; reimbursement for biologics may vary by insurance carrier or type. Notably, a high burden of disease among patients with HS is associated with lower annual income and income growth, higher risk of leaving the workforce, more days of work loss, and higher indirect costs [35], thus resulting in greater difficulty in obtaining insurance.

The potential barriers to biologic use may include several factors [36]. Clinicians may be hesitant to use biologics due to lack of familiarity, unclear treat-to-target paradigms, high prior authorization burden, and limited access to specialists with expertise in HS. Patient related factors may include hesitancy regarding injections or side effects, lack of trust in medical providers, delayed diagnosis, and previous experience with ineffective treatments. Financial burden is also a barrier to biologic exposure, as insurance may not cover the use of these expensive treatments, even though effective management of HS to minimize or prevent flares may decrease the need to treat HS in high-cost acute care settings. Early management may also be cost effective for patients and healthcare systems and could be a useful area to explore in future research.

There is a higher prevalence of HS in the Medicaid population, and those with HS have more frequent exposure to opioids, lower overall frequency of biologic use, and higher comorbidity burden compared with CCAE+MDCR patients. Although African Americans comprise 13.6% of the US population [37], 41.2% are enrolled in Medicaid or some other type of public health insurance [38], and they are disproportionately affected by HS [5, 39]. The differences in dermatologist visits and treatment exposures in CCAE+MDCR and Medicaid patients also highlight the need for further research into regional differences and the impact of socioeconomic status (SES) in the population of patients with HS in the USA, particularly since patients with HS are at increased risk of having a low SES compared with patients without HS [40]. Those with a low SES are also more likely to have Medicaid or other public health insurance (64.3%) [38], have poor-quality health care, and access health care less often [41]. Owing to the high costs of HS care (e.g., dermatologist visits, incision/drainage procedures), patients with HS who have a lower SES may not have access to regular care until their symptoms are severe enough to require treatment in the emergency room. Furthermore, the disease burden of HS may force some individuals into a lower SES bracket, and it may be worthwhile to explore the potential of early therapy, including biologics, in preventing individuals from shifting to a lower SES.

Strengths and Limitations

Data from routine clinical practice can provide useful insights on disease occurrence, patient characteristics, and treatment patterns. The use of claims data and the large sample size within these databases allow for a reliable assessment of changes in care over time and the current standard of care for patients with HS in the USA. This evaluation may also allow for areas of improvement to be identified to ensure patients with HS have access to appropriate treatments. Utilizing at least one ICD-9 code for HS balances accuracy and adequate power with a positive predictive value of 79% [25], and the use of two ICD codes may further increase accuracy [42].

However, claims databases have some limitations. The databases used rely on accurate ICD coding. The underdiagnosis or misdiagnosis of HS may result in missed cases. Records of medication use are based on dispensed medications rather than medication consumed by or administered to the patient. Treatment indications for prescriptions are not captured in these databases and treatment exposures do not

specify use for HS management. The CCAE+MDCR data are limited to patients who are commercially insured and those outside the working population will be underrepresented in the database, limiting the generalizability of the data. Finally, the international generalization of the results may be limited due to potential differences in the USA compared with other world regions.

CONCLUSIONS

Over the last decade, HS care and treatment has dramatically evolved, accompanied by an increase in interest and awareness of the disease, the emergence of new treatments, including biologics, and an increase in documented HS prevalence. However, there is still not an optimal healthcare pathway available for many patients with HS, and diagnosis is often substantially delayed. In addition, dermatology visits and exposure to biologics are still low overall, though an increase can be observed for a select group of patients. Owing to the high disease burden faced by patients with HS, increasing the exposure of patients to dermatologists for comprehensive care, including evaluation of whether a patient is an appropriate candidate for advanced therapies, is likely to improve the care and outcomes of these patients.

ACKNOWLEDGEMENTS

Funding. Sponsorship for this study and Rapid Service Fee were funded by UCB Pharma. Support for third-party writing assistance for this article, provided by Zoha Naveed, MBiochem and Hannah Brechka, PhD, Costello Medical, UK, was funded by UCB Pharma in accordance with Good Publication Practice (GPP3) guidelines (http://www.ismpp.org/gpp3).

Medical Writing, Editorial, and Other Assistance. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany for publication coordination, Anna Sheahan for contributions to this study, and Zoha Naveed, MBiochem and Hannah Brechka, PhD, from Costello Medical, UK, for medical writing and editorial assistance based on the authors' input and direction. This study was funded by UCB Pharma.

Authorship. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Author Contributions. Substantial contributions to study conception and design: AG, HBN, AA, PH, JLH, VYS, JW, TT, IP, ABK; substantial contributions to analysis and interpretation of the data: AG, HBN, AA, PH, JLH, VYS, JW, TT, JR, AJ, IP, ABK; drafting the article or revising it critically for important intellectual content: AG, HBN, AA, PH, JLH, VYS, JW, TT, JR, AJ, IP, ABK; final approval of the version of the article to be published: AG, HBN, AA, PH, JLH, VYS, JW, TT, JR, AJ, IP, ABK.

Disclosures. AG: Received research grants from AbbVie, UCB Pharma, and National Psoriasis Foundation; received honoraria from AbbVie, Aclaris Therapeutics, Anaptys Bio, Aristea Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Incyte, InflaRx, Insmed, Janssen, Novartis, Pfizer, UCB Pharma, Union Therapeutics and Viela Biosciences for advisory board services; co-copyright holder of the HS-IGA and HiSQoL instruments. HBN: Grant support from AbbVie; consulting fees from 23andme, Abbvie, Nimbus Therapeutics, and DAVA Oncology; advisory board fees from Boehringer Ingelheim, and Novartis; investigator for Pfizer; Associate Editor for JAMA Dermatology; uncompensated board member of the US Hidradenitis Suppurativa Foundation. AA: On the Board of Directors for the Hidradenitis Suppurativa Foundation; served as consultant for Abbvie, Boehringer Ingelheim, InflaRx, Janssen, Novartis, and UCB Pharma; principal investigator for Boehringer Ingelheim, and Processa. PH: On the Board of Directors for

the Hidradenitis Suppurativa Foundation; served as an advisor and speaker for AbbVie. JLH: On the Board of Directors for the Hidradenitis Suppurativa Foundation; served as a speaker for AbbVie and an advisor for Abbvie, Boehringer Ingelheim, Novartis, and UCB Pharma. VYS: On the Board of Directors for the Hidradenitis Suppurativa Foundation; stock shareholder of Learn Health; served as an advisory board member, investigator, speaker, and/or received research funding from AbbVie, Altus Lab, Burt's Bees, Dermira, Eli Lilly, Galderma, GpSkin, Kiniksa, LEO Pharma, Menlo Therapeutics, MYOR, Novartis, Pfizer, Polyfin, Regeneron, Sanofi-Genzyme, Skin Actives Scientific, SUN Pharma, TARGET-DERM, and UCB Pharma. JW: Research grants from AbbVie, Amgen, Avillion, Boehringer Ingelheim, Bristol Myers Squibb, ChemoCentryx, Dermira, GSK, InflaRx, LEO Pharma, Janssen, Novartis, Pfizer, Regeneron, Sanofi, and UCB Pharma; consulting fees from AbbVie, Janssen, Novartis, Regeneron, Sanofi, and UCB Pharma; speaker's bureau from AbbVie, Janssen, Novartis, Regeneron, and Sanofi. TT, JR, AJ: Employees of UCB Pharma. IP: Employee and shareholder of UCB Pharma. ABK: Consultant and investigator for Abbvie, Bristol Myers Squibb, Janssen, Eli Lilly, Novartis, Pfizer, and UCB Pharma; investigator for Incyte and Anapyts Bio; consultant for Bayer, Boehringer Ingleheim, Ventyx, Moonlake, Lilly, Concert, EvoImmune, Sonoma Bio, Sanofi, and receives fellowship funding from Janssen and Abbvie; serves on Board of Directors for Almirall.

Compliance with Ethics Guidelines. Ethics committee approval was not required as this study utilized deidentified claims data. The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Consent from patients for the use of their data in the study and its publication was also not required as this was a retrospective cohort study that used deidentified claims data.

Data Availability. The dataset (IBM® MarketScan® Research Databases) generated and/or analyzed during the current study are not publicly available but are available from IBM® on reasonable request.

REFERENCES

1. Napolitano M, Megna M, Timoshchuk EA, et al. Hidradenitis suppurativa: from pathogenesis to diagnosis and treatment. Clin Cosmet Investig Dermatol. 2017;10:105–15.

2. Zouboulis CC. Adalimumab for the treatment of hidradenitis suppurativa/acne inversa. Expert Rev Clin Immunol. 2016;12:1015–26.

3. Ballard K, Shuman VL. Hidradenitis suppurativa. In: StatPearls. Treasure Island (FL): StatPearls Publishing 2022.

4. Navrazhina K, Frew JW, Gilleaudeau P, Sullivan-Whalen M, Garcet S, Krueger JG. Epithelialized tunnels are a source of inflammation in hidradenitis suppurativa. J Allergy Clin Immunol. 2021;147:2213–24.

5. Garg A, Kirby JS, Lavian J, Lin G, Strunk A. Sex- and age-adjusted population analysis of prevalence estimates for hidradenitis suppurativa in the United States. JAMA Dermatol. 2017;153:760–4.

6. Ingram JR. The epidemiology of hidradenitis suppurativa. Br J Dermatol. 2020;183:990–8.

7. Dufour DN, Emtestam L, Jemec GB. Hidradenitis suppurativa: a common and burdensome, yet under-recognised, inflammatory skin disease. Postgrad Med J. 2014;90:216–21.

8. Ingram JR, Bettoli V, Espy JI, et al. Unmet clinical needs and burden of disease in hidradenitis suppurativa: real-world experience from EU5 and US. J Eur Acad Dermatol Venereol. 2022;36:1597–605.

9. Montero-Vilchez T, Diaz-Calvillo P, Rodriguez-Pozo JA, et al. The burden of hidradenitis suppurativa signs and symptoms in quality of life: systematic review and meta-analysis. Int J Environ Res Public Health. 2021;18:6709.

10. Onderdijk AJ, van der Zee HH, Esmann S, et al. Depression in patients with hidradenitis suppurativa. J Eur Acad Dermatol Venereol. 2013;27:473–8.

11. Margesson LJ, Danby FW. Hidradenitis suppurativa. Best Pract Res Clin Obstet Gynaecol. 2014;28:1013–27.

12. Moloney S. The challenges of wound management for hidradenitis suppurativa. Br J Nurs. 2022;31:S34-s41.

13. Matusiak Ł. Profound consequences of hidradenitis suppurativa: a review. Br J Dermatol. 2020;183:e171–7.

14. Smith HS, Chao JD, Teitelbaum J. Painful hidradenitis suppurativa. Clin J Pain. 2010;26:435–44.

15. Sabat R, Jemec GBE, Matusiak Ł, Kimball AB, Prens E, Wolk K. Hidradenitis suppurativa. Nat Rev Dis Primers. 2020;6:18.

16. Reddy S, Strunk A, Jemec GBE, Garg A. Incidence of myocardial infarction and cerebrovascular accident in patients with hidradenitis suppurativa. JAMA Dermatol. 2020;156:65–71.

17. Garg A, Malviya N, Strunk A, et al. Comorbidity screening in hidradenitis suppurativa: evidence-based recommendations from the US and Canadian Hidradenitis Suppurativa Foundations. J Am Acad Dermatol. 2022;86:1092–101.

18. Reddy S, Strunk A, Garg A. Comparative overall comorbidity burden among patients with hidradenitis suppurativa. JAMA Dermatol. 2019;155:797–802.

19. Reddy S, Strunk A, Garg A. All-cause mortality among patients with hidradenitis suppurativa: a population-based cohort study in the United States. J Am Acad Dermatol. 2019;81:937–42.

20. Goldburg SR, Strober BE, Payette MJ. Hidradenitis suppurativa: current and emerging treatments. J Am Acad Dermatol. 2020;82:1061–82.

21. Deckers IE, Prens EP. An update on medical treatment options for hidradenitis suppurativa. Drugs. 2016;76:215–29.

22. U.S. FDA, Orphan Drug Designations and Approvals. https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=446414. Accessed 15 July 2022.

23. Mitra D, Chopra A, Saraswat N, Mitra B, Talukdar K, Agarwal R. Biologics in dermatology: off-label indications. Indian Dermatol Online J. 2020;11:319–27.

24. Garg A, Neuren E, Cha D, et al. Evaluating patients' unmet needs in hidradenitis suppurativa: results from the Global Survey Of Impact and Healthcare Needs (VOICE) Project. J Am Acad Dermatol. 2020;82:366–76.

25. Strunk A, Midura M, Papagermanos V, Alloo A, Garg A. Validation of a case-finding algorithm for hidradenitis suppurativa using administrative coding from a clinical database. Dermatology. 2017;233:53–7.

26. Narla S, Lyons AB, Hamzavi IH. The most recent advances in understanding and managing hidradenitis suppurativa. F1000Res. 2020;9:1049.

27. Marvel J, Vlahiotis A, Sainski-Nguyen A, Willson T, Kimball A. Disease burden and cost of hidradenitis suppurativa: a retrospective examination of US administrative claims data. BMJ Open. 2019;9:e030579.

28. Garg A, Besen J, Legler A, Lam CS. Factors associated with point-of-care treatment decisions for hidradenitis suppurativa. JAMA Dermatol. 2016;152:553–7.

29. Garg A, Lavian J, Strunk A. Low utilization of the dermatology ambulatory encounter among patients with hidradenitis suppurativa: a population-based retrospective cohort analysis in the USA. Dermatology. 2017;233:396–8.

30. Dayer LE, Painter JT, McCain K, King J, Cullen J, Foster HR. A recent history of opioid use in the US: three decades of change. Subst Use Misuse. 2019;54:331–9.

31. Lee B, Zhao W, Yang KC, Ahn YY, Perry BL. Systematic evaluation of state policy interventions targeting the US opioid epidemic, 2007–2018. JAMA Netw Open. 2021;4: e2036687.

32. Reddy S, Orenstein LAV, Strunk A, Garg A. Incidence of long-term opioid use among opioid-naive patients with hidradenitis suppurativa in the United States. JAMA Dermatol. 2019;155:1284–90.

33. Garg A, Papagermanos V, Midura M, Strunk A, Merson J. Opioid, alcohol, and cannabis misuse among patients with hidradenitis suppurativa: a population-based analysis in the United States. J Am Acad Dermatol. 2018;79:495-500.e1.

34. Orenstein LAV, Wright S, Strunk A, Garg A. Low prescription of tumor necrosis alpha inhibitors in hidradenitis suppurativa: a cross-sectional analysis. J Am Acad Dermatol. 2021;84:1399–401.

35. Tzellos T, Yang H, Mu F, Calimlim B, Signorovitch J. Impact of hidradenitis suppurativa on work loss, indirect costs and income. Br J Dermatol. 2019;181:147–54.

36. De DR, Shih T, Fixsen D, Brooks B, Hsiao JL, Shi VY. Biologic use in hidradenitis suppurativa: patient perspectives and barriers. J Dermatol Treat. 2022;1–3.

37. Quick Facts, U.S. Census Bureau. https://www.census.gov/quickfacts/fact/table/US#. Accessed 15 July 2022.

38. Keisler-Starkey K, Bunch LN. Health insurance coverage in the United States: 2020. U.S. Census Bureau. 2021

39. Garg A, Lavian J, Lin G, Strunk A, Alloo A. Incidence of hidradenitis suppurativa in the United States: a sex- and age-adjusted population analysis. J Am Acad Dermatol. 2017;77:118–22.

40. Wertenteil S, Strunk A, Garg A. Association of low socioeconomic status with hidradenitis suppurativa in the United States. JAMA Dermatol. 2018;154:1086–8.

41. Becker G, Newsom E. Socioeconomic status and dissatisfaction with health care among chronically ill African Americans. Am J Public Health. 2003;93:742–8.

42. Kim GE, Shlyankevich J, Kimball AB. The validity of the diagnostic code for hidradenitis suppurativa in an electronic database. Br J Dermatol. 2014;171:338–42.