

Characteristics of Patients Initiating Guselkumab for Plaque Psoriasis in the Symphony Health Claims Database

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ABSTRACT

Guselkumab is approved by the Food and Drug Administration for the treatment of moderate-to-severe plaque psoriasis. However, characteristics of patients initiating guselkumab in a real-world setting are not well characterized. The present study described baseline characteristics of patients with psoriasis initiating guselkumab in the first year after approval using data from the Symphony Health Claims database. Adult patients with psoriasis with ≥1 claim for guselkumab between 7/13/2017 and 7/2/2018 were included. The index date was defined as the date of the first pharmacy claim for guselkumab. Outcomes of interest included demographics, frequency of prior biologic and non-biologic psoriasis treatments, and frequency of diagnoses or procedures during the year before guselkumab initiation (baseline period). A total of 1,520 patients were included. Mean age was 51.2 (SD 13.4) years and 53.7% of patients were female. During the baseline period, 63.9% of patients had ≥1 biologic drug claim and 66.9% were prescribed topical corticosteroids/combinations. The most common non-psoriasis diagnoses among patients with ≥1 medical claim were hypertension (25.1%), type 2 diabetes (13.4%), and hyperlipidemia (13.4%). The most common procedures reflected routine medical care. These findings describing the baseline characteristics of patients initiating guselkumab provide insights regarding variables that may impact observed treatment outcomes and may ultimately help with treatment decision making.

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INTRODUCTION

Psoriasis is a chronic dermatologic disease that affects more than 7.4 million individuals in the United States (US).[1] Biologic therapies targeting inflammatory cytokines have become an important treatment option for patients with moderate-to-severe psoriasis.[2] Several biologics that inhibit interleukin 17 (IL-17) or IL-23 have recently been approved in this indication by the Food and Drug Administration (FDA), as these cytokines are integral to the pathogenesis of psoriasis.[3,4] Guselkumab (CNTO 1959; Janssen Research & Development LLC, Spring House, PA), a novel human monoclonal antibody that inhibits IL-23, was the first biologic of its class approved by the FDA for the treatment of adult patients with moderate-to-severe plaque psoriasis.[5,6]

Describing the baseline characteristics of patients who are initiating a recently approved therapy is important to provide insights regarding variables that may impact observed treatment outcomes, which may ultimately play a role in treatment decision making. However, the characteristics of patients with psoriasis initiating treatment with guselkumab in a real-world setting are not well characterized. The objective of the present study was to describe the baseline characteristics and treatment history of patients with psoriasis who initiated guselkumab during the first year after FDA approval using real-world data from the Symphony Health Claims database.

MATERIALS AND METHODS

Patient Population

A retrospective, descriptive analysis was conducted using data from the Symphony Health Claims database. This database includes US pharmacy, diagnosis, and procedure claims collected through electronic claims processors, commercial sources, and government sources (Medicare and Medicaid). Over 93% of outpatient prescriptions dispensed in the US and territories are captured in this database.[7] Furthermore, the Symphony database is built around claims processors and therefore approximates "real-time" data, allowing for evaluation relatively soon after product approval.

The present study included patients with psoriasis aged 18 years or greater who had ≥2 psoriasis diagnoses separated by at least 30 days between 10/01/2012 and 08/31/2018. Patients were included if they had ≥1 claim for guselkumab between 7/13/2017 (the FDA approval date for guselkumab in psoriasis) and 7/2/2018. The index date was defined as the date of the first pharmacy claim for guselkumab and the baseline period was defined as the 365-day period prior to the index date. Patients were excluded if they had claims for >1 biologic on the index date or if they had claims with potential day supply problems or out-of-range/uninterpretable quantities.

Outcomes of Interest

Outcomes of interest included baseline demographics (age, sex, US region, type of health insurance, and presence of other biologic-treated conditions), treatment history (use of biologic and non-biologic psoriasis treatments during the baseline period), and most frequent diagnostic (International Classification of Diseases, 10th revision [ICD-10]) and procedural (Current Procedural Terminology [CPT] and Healthcare Common Procedure Coding System [HCPCS]) claims during the baseline period.

Statistical Analysis

Categorical variables were summarized using frequencies or percentages and continuous variables were summarized using means and standard deviations. All analyses were conducted using SAS for Windows 9.4 (Cary, NC).

RESULTS

Baseline Characteristics

A total of 1,520 patients with psoriasis who had initiated guselkumab during the study period were identified (Figure 1). The baseline demographics for these patients are presented in Table 1. The mean age was 51.2 (SD 13.4) years and 53.7% of patients were female. The largest proportion of patients was from the Southern US (41.3%) and the most common type of insurance at index was commercial (63.3%). Psoriatic arthritis (PsA) was the most common comorbid biologic-treated condition identified during the baseline period (14.9%).

Prior Pharmacy Claims

During the baseline period, 972 patients (63.9%) had ≥1 biologic drug claim and 206 patients (13.6%) had claims for ≥2 biologics.

TABLE 1.

Baseline Characteristics of Patients with Psoriasis who Initiated Guselkumab in the Symphony Health Claims Database

Characteristics	Patients Initiating Guselkumab (N = 1,520)
Age (years), mean (SD)	51.2 (13.4)
Female, n (%)	816 (53.7)
Regions, n (%)	
South	627 (41.3)
Northeast	439 (28.9)
Midwest	312 (20.5)
West	141 (9.3)
Unknown	1 (0.1)
Payment type on index, n (%)	
Commercial	962 (63.3)
Medicare	313 (20.6)
Assistance programs	126 (8.3)
Managed Medicaid	87 (5.7)
Medicaid	29 (1.9)
Cash	3 (0.2)
Other conditions treated with biologics present before index, n (%)	
Psoriatic arthritis	226 (14.9)
Rheumatoid arthritis	25 (1.6)
Ankylosing spondylitis	17 (1.1)
Hidradenitis suppurativa	10 (0.7)
Crohn's disease	6 (0.4)
Ulcerative colitis	5 (0.3)

Abbreviations: SD = standard deviation.

FIGURE 1. Attrition of patients included in the analysis.

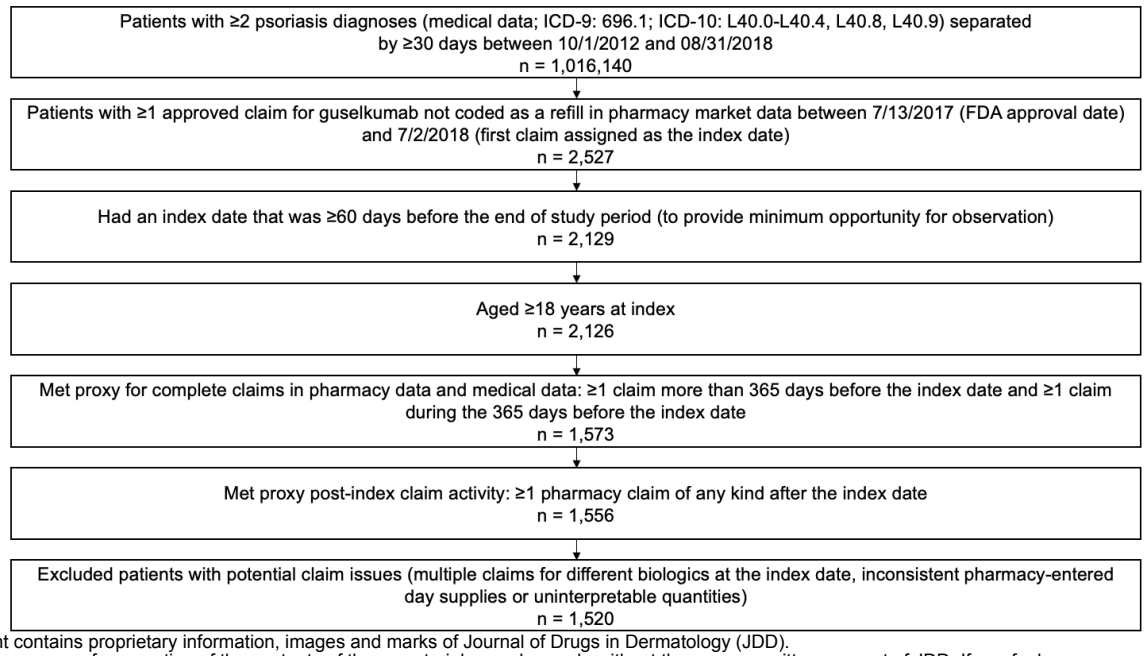
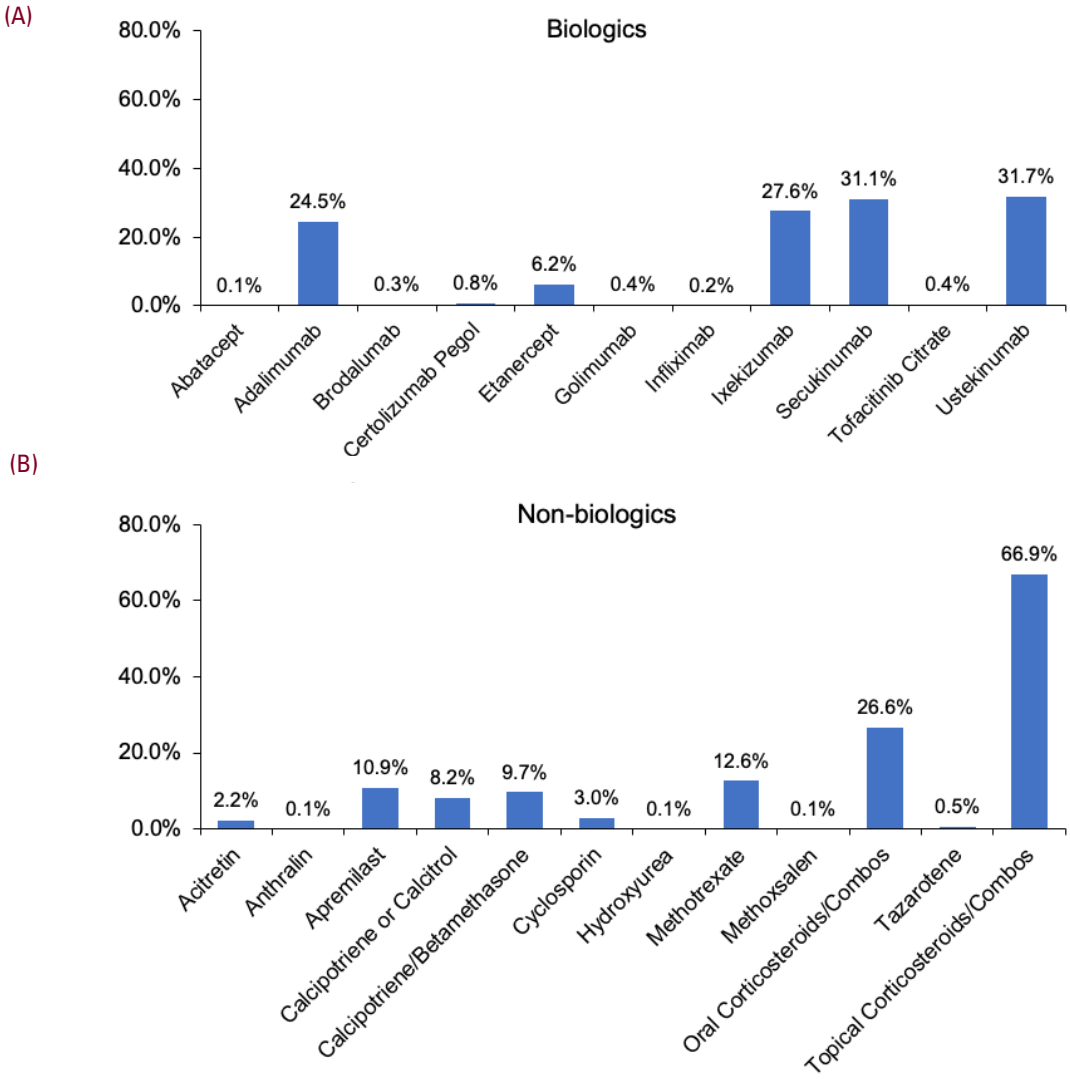


FIGURE 2. Most frequently claimed biologic (A) and non-biologic psoriasis treatments (B) during the baseline period. The percentage of patients with a claim for each biologic was assessed among those with ≥1 biologic drug claim during the baseline period. The percentage of patients with a claim for each non-biologic psoriasis treatment was assessed among the full study cohort. Patients may have had claims for multiple agents.



Among patients with ≥1 biologic claim, the most frequently prescribed biologics were ustekinumab (31.7%), secukinumab (31.1%), ixekizumab (27.6%), adalimumab (24.5%), and etanercept (6.2%) (Figure 2A). Less than 1% of patients had ≥1 claim for any other biologic.

Non-biologic drug claims were also analyzed. During the baseline period, 1,243 patients (81.8%) had ≥1 non-biologic drug claim. The most common non-biologic psoriasis drugs during the baseline period were topical corticosteroids (including combination drugs; 66.9%), oral corticosteroids/combinations (26.6%), methotrexate (12.6%), and apremilast (10.9%) (Figure 2B). Less than 10% of patients had ≥1 claim for any other non-biologic drug.

Prior Medical Claims

During the baseline period, 35.9% of patients had ICD-10 codes that indicated long-term medication use (Figure 3). The most common non-psoriasis diagnoses were primary hypertension (25.1%), type 2 diabetes without complications (13.4%), and hyperlipidemia (13.4%).

The most common procedures (based on CPT or HCPCS codes) reflected routine medical care such as outpatient office visits (15 minutes: 60.4%; 25 minutes: 49.0%), venous blood collection (40.1%), and complete blood count (32.0%) (Figure 4). In terms of specific procedures, tuberculosis tests (16.3%), A1C tests (13.2%), thyroid stimulating hormone tests (10.2%), and triamcinolone injections (6.8%) were most common.

FIGURE 3. Most common non-psoriasis diagnoses during the baseline period. The percentage of patients with a specific diagnosis reflects those with ≥1 claim that included a relevant ICD-10 code. Patients may have had claims for multiple diagnoses.

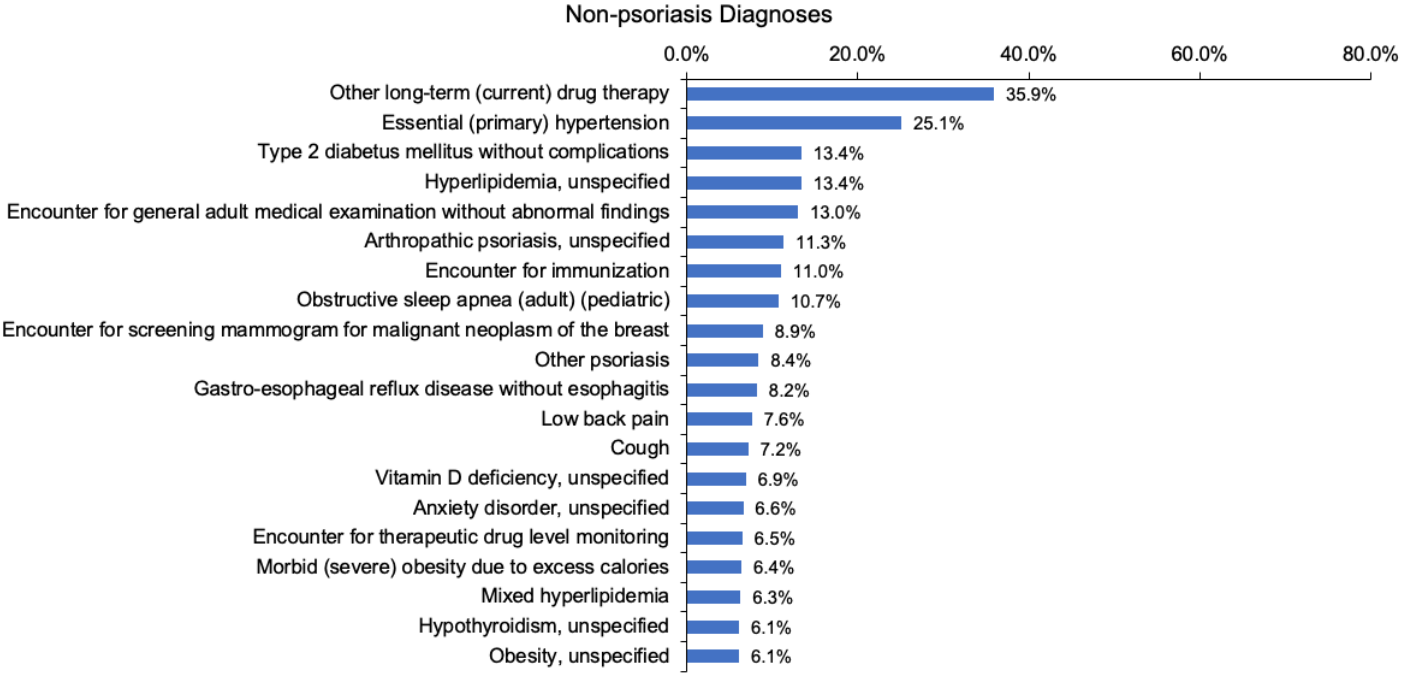
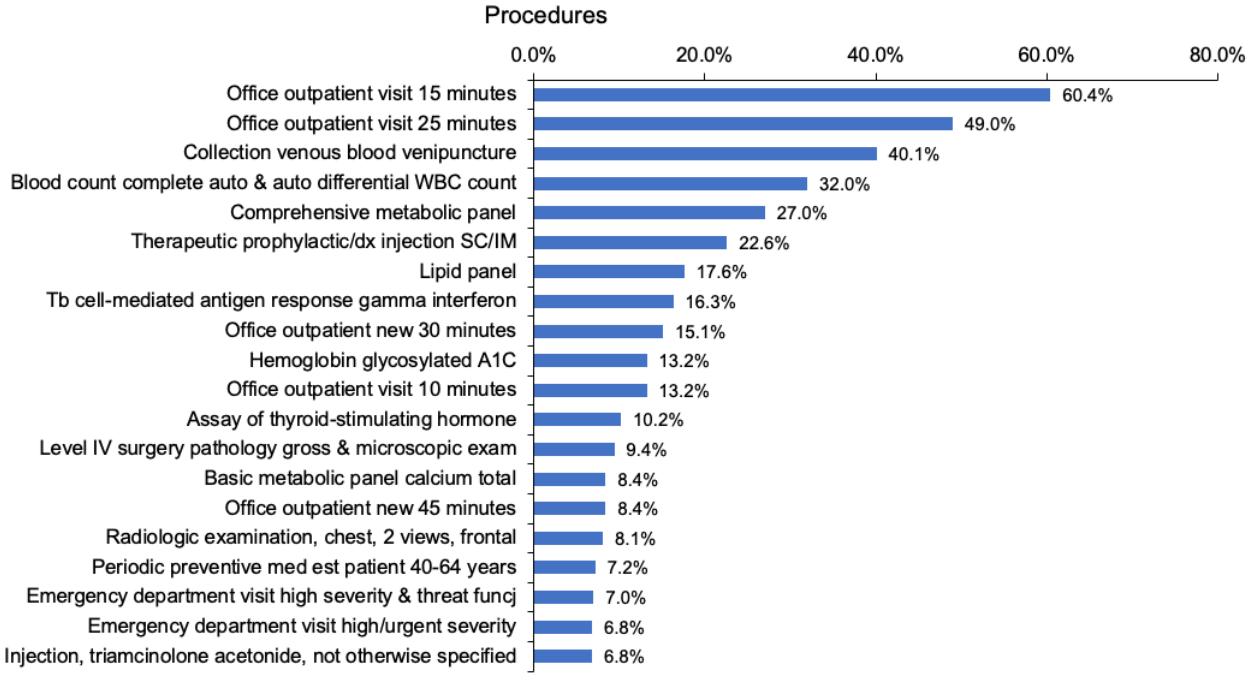


FIGURE 4. Most common procedures during the baseline period. The percentage of patients who underwent a specific procedure reflects those with ≥1 claim that included a relevant CPT or HCPCS code. Patients may have had claims for multiple procedures.



DISCUSSION

This real-world analysis described baseline demographics and treatment history of patients with psoriasis who initiated guselkumab during the first year after FDA approval using data from the Symphony Health Claims database. Baseline demographics including mean age and proportion of female patients were generally consistent with findings from other recent real-world studies of patients with psoriasis initiating biologics.[8-11] Notably, 63.9% of patients in the present study had at least one claim for another biologic during the year before initiating guselkumab. This finding is slightly lower than rates reported in previous real-world studies of patients initiating the IL-17 inhibitors ixekizumab or secukinumab (66%-88%),[8-10] which may reflect differences in study design, data sources, or in the actual proportion of patients initiating these newer agents as first-line biologic therapy.

The most common baseline comorbidities among patients with psoriasis initiating guselkumab were hypertension (25.1%), type 2 diabetes (13.4%), and hyperlipidemia (13.4%), a finding consistent with those of other recent registry and claims-based studies.[8-12] However, the rates of hypertension and hyperlipidemia among patients in the present study are lower than those reported previously, which have ranged from 32.8%-44.7% and 28.1%-48.6%, respectively.[8-12] As noted above, this finding may be associated with differences in the data or patient populations captured by various real-world data sources.

There are several important limitations of this study. As with all claims-based studies, there is a possibility of data omissions or coding errors within the database and the potential for selection bias or sampling error. Furthermore, treatment observations were based on claims for a filled prescription, which does not guarantee actual use of medication(s) by patients. Since the analysis used outpatient pharmacy data, drugs administered in an inpatient hospital setting were not included and those administered in physicians' offices or facilities may be underrepresented. In addition, the medical claims included in the analysis may be less complete than pharmaceutical data; however, it was assumed that the observations were reflective of population trends even if the absolute values were not. Finally, the dataset did not include information regarding patient insurance eligibility; therefore, proxies were implemented to support assumptions of data completeness.

CONCLUSION

The results of this real-world analysis provide an overview of the patient demographics and treatment history of patients with psoriasis who initiated guselkumab during the first year after FDA approval. These findings provide insights regarding variables that may impact treatment outcomes and may ultimately help with treatment decision making. In addition, these findings will help to inform the design of future assessments of the real-world effectiveness of guselkumab.

DISCLOSURES

T. Fitzgerald and A. Teeple are employees of Janssen Scientific Affairs, LLC, and stockholders of Johnson & Johnson, of which Janssen Scientific Affairs, LLC is a wholly owned subsidiary. EVERSANA is a paid consultant of Janssen and supported in the writing and submission of this manuscript. C. Kozma and T. Slaton received research funding from Janssen Scientific Affairs, LLC.

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