Real-world vs Guideline-Based Treatments for Chronic Spontaneous Urticaria Among Commercially Insured vs Medicaid Patients in the United States

126

Vincent Garmo,[1] Arpamas Seetasith,[1] Sheila R. Reddy,[2] Eunice Chang,[2] Marian H. Tarbox,[2] Michael Holden,[1] Thomas B. Casale[3]

[1]Genentech, Inc., South San Francisco, CA, USA; [2]Partnership for Health Analytic Research, Beverly Hills, CA, USA; [3]University of South Florida, Tampa, FL, USA

Background

- Chronic spontaneous urticaria (CSU) is characterized by itchy wheals (hives) and/or angioedema for >6 weeks and can compromise quality of life, interfere with daily activities, and incur significant health care resource use and costs.[1,2]
- The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guidelines for CSU recommend second-generation H1 antihistamines as first-line treatment of CSU and the biologic therapy omalizumab (300 mg every 4 weeks, independent of immunoglobulin E [IgE] levels) as second-line treatment (for patients who do not show clinical benefit).[3]
- Although guidelines and approved treatments are available, data suggest that CSU may often be uncontrolled,[4] and there is limited information regarding real-world treatment patterns.

Objectives

- To examine how real-world treatment of CSU among commercially insured and Medicaid patients aligns with current global treatment guidelines.

Methods

- This retrospective analysis used the Merative™ MarketScan® Commercial Database (January 1, 2016–June 30, 2020) and MarketScan Multi-State Medicaid Database (January 1, 2014–December 31, 2019).
- Patients aged ≥12 years diagnosed with CSU during the study period were included (index diagnosis).
  - The index claim was defined as the date of the first claim for an urticaria International Classification of Diseases code in the identification period (commercial database: January 1, 2017–June 30, 2019; Medicaid database: January 1, 2015–December 31, 2018).
  - An additional claim with a diagnosis of urticaria or angioedema ≥6 weeks from and <1 year of the index date was required.
  - Patients with ≥1 year of continuous health plan enrollment before and after initial CSU diagnosis were included; patients were followed for ≥1 year until the end of enrollment or study end.
- Patients with a diagnosis of urticaria or who received a CSU treatment in the baseline period (1 year before the index date) and patients who had a diagnosis of asthma or other urticaria during the study period were excluded.
- Outcomes included:
  - Medications for CSU in the first year after initial CSU diagnosis
  - Number of CSU medications before omalizumab (based on information on treatments prescribed and reimbursable by health plans only)
  - Oral corticosteroid (OCS) use
  - Dermatologist/allergist visits.

Results

Patient Characteristics

- The study cohort consisted of 10 764 patients newly diagnosed with CSU; 9936 were commercially insured and 828 had Medicaid (**Table 1**).

Table 1. Patient Characteristics

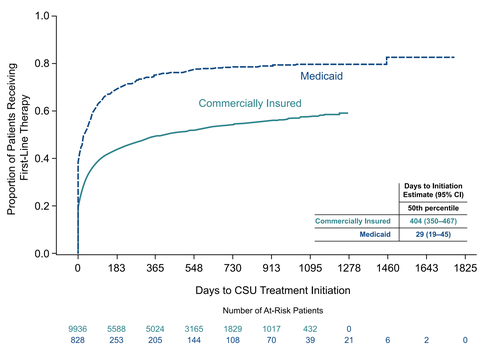
Characteristic	Commercially Insured n=9936	Medicaid n=828
Age, years, mean (SD)	40.1 (16.3)	25.9 (14.7)
Female, n (%)	6898 (69.4)	603 (72.8)
Charlson Comorbidity Index, mean (SD)	0.30 (0.95)	0.31 (1.01)
Follow-up, days, median	665	819
Received ≥1 medication for CSU,* n (%)	5341 (53.8)	650 (78.5)

CSU, chronic spontaneous urticaria.
*During the variable follow-up period.

Treatment for CSU

- The time to first-line therapy was shorter for Medicaid patients than for those who were commercially insured (median, 29 vs 404 days; **Figure 1**).

Figure 1. Time to First Observed CSU Therapy From the Index Date



CSU, chronic spontaneous urticaria.
Follow-up time was variable.

- A lower proportion of commercially insured patients received prescription treatment within the first year of initial CSU diagnosis compared with Medicaid patients (49.4% vs 75.2%; **Table 2**).

Table 2. Most Common Treatment for CSU Within the First Year of Initial CSU Diagnosis

Patients, n (%)	Commercially Insured n=9936	Medicaid n=828
Treated with any CSU medication	4912 (49.4)	623 (75.2)
First-generation H1 antihistamines	2695 (27.1)	300 (36.2)
Second-generation H1 antihistamines	917 (9.2)	442 (53.4)
H2 antagonists	1832 (18.4)	249 (30.1)
Leukotriene modifiers	1604 (16.1)	95 (11.5)
Omalizumab	556 (5.6)	28 (3.4)
Cyclosporine	47 (0.5)	3 (0.4)
Other anti-inflammatory agents, immunosuppressants, or biologics	286 (2.9)	11 (1.3)
OCS use	5386 (54.2)	463 (55.9)
Topical corticosteroid use	2843 (28.6)	221 (26.7)

CSU, chronic spontaneous urticaria; OCS, oral corticosteroid.

- Almost half of patients used OCS long term (**Table 3**).

Table 3. OCS Use

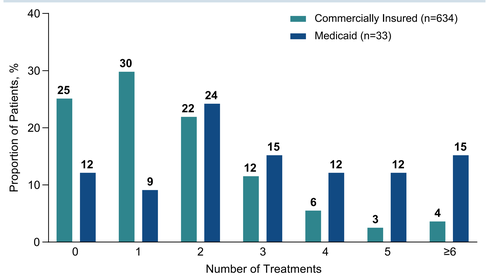
	Commercially Insured n=9936	Medicaid n=828
Patients using an OCS, n (%)	5984 (60.2)	511 (61.7)
Days to first fill among OCS users, mean (SD)	106.3 (195.1)	102.0 (217.9)
Chronic OCS use (claims within >5 days of supply), n (%)	4781 (48.1)	349 (42.1)
Total days of supply, mean (SD)	13.7 (49.8)	12.7 (70.5)

OCS, oral corticosteroid.
Follow-up was variable.

Omalizumab, Cyclosporine, and Immunosuppressant/Modulator Use

- A greater proportion of commercially insured patients received omalizumab as earlier treatment compared with those on Medicaid (**Figure 2**).
  - The mean (SD) omalizumab treatment line was 2.7 (1.7) and 4.2 (2.4) for commercially insured and Medicaid patients, respectively.

Figure 2. Number of Reimbursable Treatments Received Before Omalizumab



Follow-up was variable. Over-the-counter medications were not included. For patients with 0 prior treatments, omalizumab was the first observed reimbursed treatment in the claims data. For this analysis, a second-generation H1 antihistamine dose increase was considered to be an additional line of therapy. 634 (6.4%) commercially insured patients and 33 (4.0%) Medicaid patients received omalizumab during the variable follow-up period.

- Only a small proportion of patients received cyclosporine and/or other immunosuppressants or biologics before omalizumab (**Table 4**).

Table 4. Cyclosporine and Immunosuppressant/Modulator Use Before Omalizumab

Patients, n (%)	Commercially Insured n=634	Medicaid n=33
Cyclosporine	16 (2.5)	1 (3.0)
Other anti-inflammatory agents, immunosuppressants, or biologics	30 (4.7)	1 (3.0)

Follow-up was variable.

Allergist/Dermatologist Visits

- A higher proportion of commercially insured patients visited a specialist compared with Medicaid patients (73.8% vs 50.1%; **Table 5**).

Table 5. Allergist/Dermatologist Visits

	Commercially Insured n=9936	Medicaid n=828
Patients with an allergist/dermatologist visit, n (%)	7334 (73.8)	415 (50.1)
Number of visits among utilizers		
Mean (SD)	4.4 (10.0)	3.2 (12.5)
Median	2	1

Limitations

- Over-the-counter medications were not captured, and lines of treatment presented were based on prescribed and reimbursed medications only.
- CSU severity and treatment responses that may influence treatment decision making were not available in the claims database.

Conclusions

- In this real-world claims analysis, adherence to treatment-based guidelines for CSU was generally low both in commercially insured and Medicaid patients.
  - There was high prevalence of chronic OCS use, even though international guidelines recommend against long-term use of systemic glucocorticosteroids.[3]
  - Use of omalizumab is generally low and, for some patients, omalizumab was prescribed later in the treatment course than is recommended by international guidelines.[3]
- There were some differences between commercially insured and Medicaid patients.
  - Omalizumab was prescribed at lower rates and later in the observed treatment course for Medicaid versus commercially insured patients.
  - More commercially insured patients saw a specialist than did Medicaid patients, which may impact guideline-driven treatment decisions.
- In summary, we found that treatment of CSU does not always follow recommended guidelines, even though guideline-driven therapy may help reduce the use of OCS and improve patient outcomes.

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Disclosures

VG, AS, MH: employees of Genentech, Inc.; shareholders in F. Hoffmann-La Roche Ltd. **SRR, EC, MHT:** employees of Partnership for Health Analytic Research, a health services research company paid to conduct the research described in this poster. **TBC:** consultant and speaker bureau member for Genentech, Inc.; consultant for Novartis Pharmaceuticals Corporation.

Acknowledgments

This analysis was funded by Genentech, Inc., a member of the Roche Group. Medical writing assistance was provided by Natalie Roberts, MSc, of Envision Pharma Group, and funded by Genentech, Inc., a member of the Roche Group.

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Presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) 2023 Annual Scientific Meeting, February 24–27, 2023, San Antonio, TX, USA