Real-world Treatment Patterns for Chronic Spontaneous Urticaria: Is Omalizumab Associated With Reduced Corticosteroid Use?

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

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

Background

- Chronic spontaneous urticaria (CSU) is a debilitating disorder characterized by itchy wheals (hives) and/or angioedema for >6 weeks with no specific cause[1] that compromises quality of life.[2]
- The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guidelines for CSU[2] recommend first-line treatment with second-generation H1 antihistamines and second-line treatment (for patients who do not show benefit) with the biologic therapy omalizumab (300 mg every 4 weeks, independent of immunoglobulin E [IgE] levels).
  - H1 antihistamines and omalizumab are the only US Food and Drug Administration (FDA)-approved treatments for CSU.
    - Use of high-dose and long-term oral corticosteroids (OCS) is not a recommended[2] or FDA-approved treatment for CSU.
- However, CSU is often undertreated[3] and evidence of real-world treatment patterns is limited.

Objective

- To describe treatment patterns, including for omalizumab and OCS, for patients with CSU in the real world.

Methods

- This retrospective cohort study utilized the Merative™ MarketScan® Commercial Database (January 1, 2016 to June 30, 2020) and MarketScan® Multi-State Medicaid Database (January 1, 2014 to December 31, 2019).
- Patients ≥12 years of age diagnosed with CSU during the study period were included (index-diagnosis).
  - Index claim was defined as the date of the first claim for an urticaria code in the identification period (commercial database: January 1, 2017 to June 30, 2019; Medicaid database: January 1, 2015 to December 31, 2018).
  - A claim with a diagnosis of urticaria or angioedema ≥6 weeks from and within 1 year of the index was required to confirm a diagnosis of CSU.
- Patients with urticaria diagnosis or who received a CSU treatment in the baseline period (1 year prior to the index date), and patients who had a diagnosis of asthma or other urticaria after index were excluded.
- Patients with ≥1 year of continuous health plan enrollment pre and post initial CSU diagnosis were included; patients were followed for ≥1 year until the end of enrollment or study end.
- Outcomes included medications for CSU and number of CSU medications prior to omalizumab (based on information on treatments prescribed and reimbursable by health plans only), OCS use, and dermatologist/allergist visits.
  - Outcomes are presented for a variable follow-up period.
  - Over-the-counter medications were not captured.
- Use of OCS pre and post omalizumab treatment initiation was annualized and assessed among patients who had an observable period of ≥1 year after omalizumab initiation.
- All study outcomes were descriptive.

Results

Patient Characteristics

- Study cohort consisted of 10,764 patients newly diagnosed with CSU: 9,936 were commercially insured and 828 had Medicaid (**Table 1**).

Table 1. Patient Characteristics

	Study Cohort N=10,764
Age, y, mean (SD)	39.0 (16.6)
Female, n (%)	7,501 (69.7)
Follow-up, d, mean (SD)	728.9 (263.3)
Charlson Comorbidity Index, mean (SD)	0.30 (0.95)

Treatment for CSU

- Half of patients received ≥1 medication for CSU (**Table 2**), with 51.4% within 1 year of initial CSU diagnosis (data not shown).
  - Treatment with first-generation H1 antihistamines was most common.
- Time to first CSU treatment (from index-diagnosis) among utilizers was 96.3 days.

Table 2. Treatment for CSU

	Study Cohort N=10,764
Received any medication, n (%)	5,991 (55.7)
First-generation H1 antihistamines	3,384 (31.4)
Second-generation H1 antihistamines	1,474 (13.7)
H2 antagonists	2,294 (21.3)
Leukotriene modifiers	1,927 (17.9)
Omalizumab	667 (6.2)
Cyclosporine	64 (0.6)
Other anti-inflammatories, immunosuppressants, or biologics	430 (4.0)
Days from index-diagnosis to start CSU treatment among utilizers, mean (SD)	96.3 (173.9)

CSU, chronic spontaneous urticaria. Note: follow-up was variable. First-generation H1 antihistamine: not recommended as first-line agent because of its potentially serious side effects; H2 antihistamine, leukotriene receptor antagonist, and immunosuppressive: not listed in the treatment algorithm and have low levels of evidence to support use; cyclosporine: recommended as third-line treatment.

Omalizumab Use

- Among omalizumab users, most patients received omalizumab as first, second, or third CSU treatment (**Table 3**).
  - The mean (SD) treatment number was 2.8 (1.7).

Table 3. Number of Reimbursable Treatments Received Prior to Omalizumab

	Patients on Omalizumab N=667
0 (omalizumab as 1st treatment)	163 (24.4)
1 (omalizumab as 2nd treatment)	192 (28.8)
2 (omalizumab as 3rd treatment)	147 (22.0)
3 (omalizumab as 4th treatment)	78 (11.7)
4 (omalizumab as 5th treatment)	39 (5.8)
5 (omalizumab as 6th treatment)	20 (3.0)
≥6 (omalizumab as 7th+ treatment)	28 (4.2)

Note: follow-up was variable. Over-the-counter medications were not included.

OCS Use

- Over half of patients used OCS post CSU diagnosis (**Table 4**).
  - Most patients (5,130/6,495; 79.0%) with OCS use had chronic OCS use.

Table 4. OCS Use

	Study Cohort N=10,764
OCS use, n (%)	6,495 (60.3)
Days to first fill among utilizers, mean (SD)	105.9 (97.0)
Chronic OCS use (claims with >5 days of supply), n (%)	5,130 (47.7)

OCS, oral corticosteroid. Note: follow-up was variable.

Dermatologist/Allergist Visits

- Most patients had a visit to a dermatologist/allergist after diagnosis of CSU (**Table 5**).
  - Patients had a median of 2 visits.

Table 5. Dermatologist/Allergist Visits

	Study Cohort N=10,764
Patients with a dermatologist/ allergist visit, n (%)	7,749 (72.0)
Number of visits among utilizers	
Mean (SD)	4.3 (10.2)
Median	2

Note: follow-up was variable.

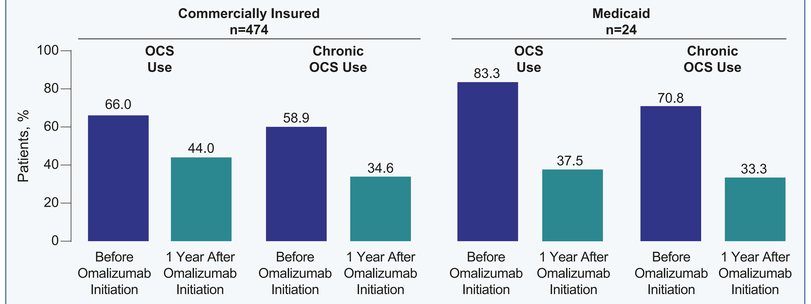
Patients on Omalizumab

- Of all patients treated with omalizumab (n=667), 501 patients had 1-year post-omalizumab follow-up.
  - **There was a mean (SD) of 4.6 (4.4) months from CSU diagnosis to omalizumab initiation.**

OCS Use for Patients on Omalizumab

- Both use of OCS and chronic OCS use decreased from before initiation of omalizumab to 1 year after initiation (**Figure 1**).

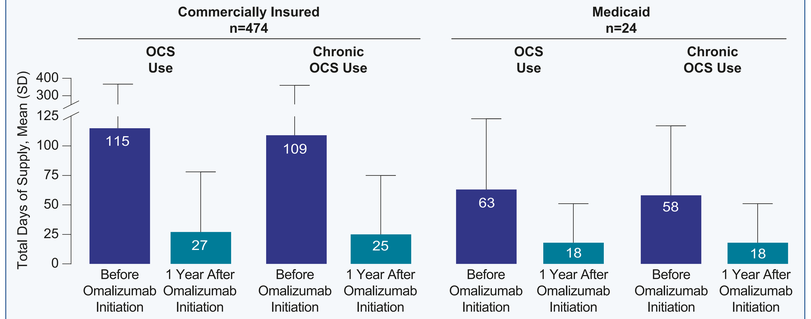
Figure 1. Use of OCS Before and After Omalizumab Initiation



CSU, chronic spontaneous urticaria; OCS, oral corticosteroid. Patients had various time between index CSU diagnosis and omalizumab initiation. Chronic OCS refers to OCS claims with >5 days of supply.

- The mean total days of supply of OCS and chronic OCS decreased from before initiation of omalizumab to 1 year after initiation (**Figure 2**).

Figure 2. Supply of OCS Before and After Omalizumab Initiation



CSU, chronic spontaneous urticaria; OCS, oral corticosteroid. Patients had various time between index CSU diagnosis and omalizumab initiation. Chronic OCS refers to OCS claims with >5 days of supply. 3 patients who started omalizumab on the index date (0 days before omalizumab initiation) were excluded because no annualized measure in the pre-omalizumab period can be reported.

Limitations

- This observational study relied on codes from claims data for specific insurance populations and therefore was subject to issues with external validity, selection bias, and misclassification bias.
- In addition, our analysis only captured patients who have had an encounter with the health care system.
- Finally, over-the-counter medications were not captured.

Conclusions

- This claims analysis identified potential delayed or insufficient treatment of CSU, as only half of patients received treatment within 1 year of their initial CSU diagnosis and there was evidence of high OCS use.
  - Almost one-third of patients did not see a dermatologist or allergist within 1 year of diagnosis.
  - In addition, for many patients, omalizumab was prescribed later in the treatment course.
- This suggests that treatment of CSU often does not follow recommended guidelines, even though guideline-driven therapy may help reduce the use of OCS and improve patient outcomes.
  - Future studies that explore (i) patient-reported medication use and quality of life and (ii) differences in prescribing patterns across physician specialties are warranted.

References

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Acknowledgments

- This study was funded by Genentech, Inc., a member of the Roche Group. Medical writing assistance was provided by Janelle Keys, CMPP, PhD, of Envision Pharma Group, and funded by Genentech, Inc., a member of the Roche Group.

Conflicts of Interest

- **AS**, **VG**, **MH**: employees of Genentech, Inc.; hold shares in F. Hoffmann-La Roche Ltd. **SRR**, **EC**, **MHT**: employees of PHAR (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.

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Presented at the Academy of Managed Care Pharmacy (AMCP) Nexus 2022, October 11–14, 2022, National Harbor, MD, USA