

# Epidemiology and Real-World Treatment of Chronic Graft-Versus-Host Disease Post Allogeneic Hematopoietic Cell Transplantation (HCT): A U.S. Claims Analysis

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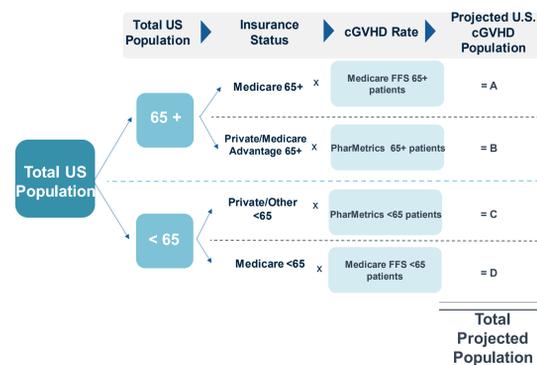
## Background

- Chronic graft-versus-host disease (cGVHD) is a complication of hematopoietic cell transplantation (HCT).<sup>1,2</sup>
- While the clinical outcomes of cGVHD are well documented, few studies have assessed its treatment practices in the real world.<sup>2</sup>
- The objectives of this study are to quantify the prevalence of cGVHD, to examine prescribing patterns, and to evaluate the healthcare cost and resource utilization (HCRU) in a real-world U.S. cGVHD population.

## Methods

- This study analyzed de-identified adjudicated claims from the Medicare Fee-For-Service 5%, a 5% random sampling of all Medicare beneficiaries, enrolled from 2013-2016 and Pharmetrics commercial 2013-2018 databases to identify cGVHD in allogeneic HCT patients. The Medicare database provides information on epidemiology and market sizing for the national Medicare population, whereas the Pharmetrics database gives insight into the patients' treatment journey for commercially insured patients.
- cGVHD was identified based on ICD-9/10 diagnosis codes for cGVHD or unspecified GVHD with a first diagnosis >180 days post HCT, or subsequent unspecified GVHD diagnosis >12 months post index diagnosis.
- GVHD prevalence was estimated by calculating age-adjusted prevalence rates within the Medicare and Pharmetrics sample populations and applying rates to the total U.S. patient subpopulations as determined by CMS and Census data (Figure 1). Prevalence estimates were based on the last complete year of both Medicare FFS and Pharmetrics data (2016).

**Figure 1: Prevalence Projection Methodology**



- Longitudinal and Line of Therapy (LOT) analyses were based on data from 2013-2018. A new LOT was defined as the addition of a systemic therapy to a patient's cGVHD regimen, regardless of prior lines of therapy or prior treatment. Treatments that stopped and restarted within 60 days were considered continuous treatment.
- Healthcare costs were calculated by adding the inpatient, outpatient, and pharmacy insurer and beneficiary paid amounts for the commercially insured population. Total HCRU was assessed using the number of inpatient and outpatient visits following the initial cGVHD diagnosis.

## Results

### Epidemiology

- Within 3 years post HCT, 42% of patients who received this procedure were diagnosed with cGVHD; 66% of the patients diagnosed with cGVHD had a prior diagnosis of acute GVHD.

- In 2016, the projected prevalence of cGVHD in the U.S. based on the Medicare FFS and Pharmetrics commercial databases was 14,017 individual patients.

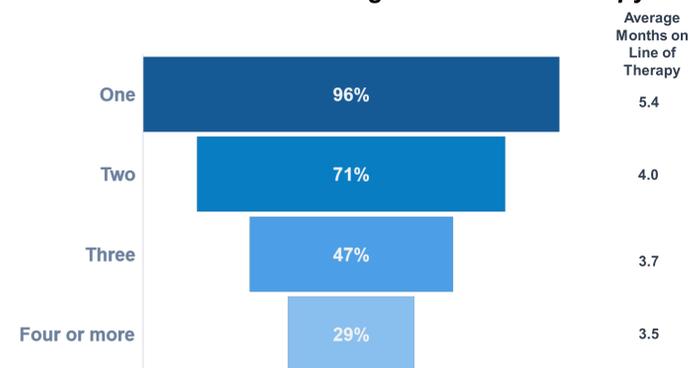
**Table 1: cGVHD Prevalent Population Demographics**

Patient Characteristics	
Average age	58 years
% Male	58%

### Treatment Patterns

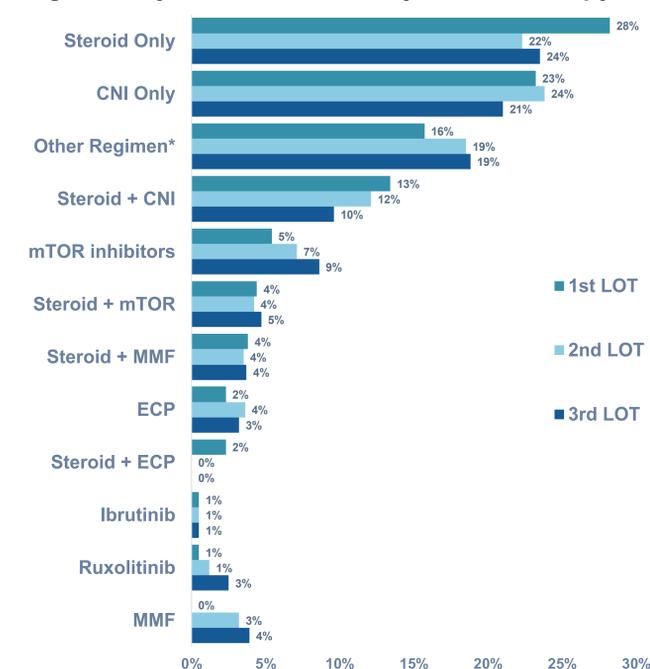
- Nearly all cGVHD patients received at least one systemic therapy; 71% and 47% of cGVHD patients progressed to a second and third LOT, respectively (Figure 2). Of patients that received a second and third LOT, the average time from diagnosis to the second and third LOT was approximately 7 months and 10 months, respectively.

**Figure 2: % cGVHD Patients Reaching Each Line of Therapy**



- Over 80% of cGVHD patients received systemic corticosteroid therapy for the treatment of cGVHD within 12 months post diagnosis. Within the 12 months post cGVHD diagnosis, most patients received a corticosteroid or a corticosteroid combination as a first LOT (57%) (Figure 3).

**Figure 3: Systemic Treatment by Line of Therapy**



- A total of 25 unique therapeutic agents and over 150 combinations were used in second and third LOT.
- Newer agents are used infrequently across first LOT and their utilization has not exceeded 1-3% of patients through their first three lines of therapy in the patients captured in Pharmetrics commercial database through June 2018.

### Healthcare Resource Utilization

- In the 12 months post diagnosis, cGVHD patients had an average of 21 inpatient and outpatient visits (3 inpatient and 18 outpatient visits) that were associated with a cGVHD diagnosis code.
- In 2016, the average total annual cost per commercially insured cGVHD patient was \$291,357 (Table 2). Costs include all costs incurred by patients who diagnosed with cGVHD and may include costs associated with non-cGVHD events.

**Table 2: Cost and Healthcare Resource Utilization**

Annual Cost per cGVHD patient (2016)	
Insurer Paid	\$281,459
Beneficiary Paid	\$9,898
Healthcare Resource Utilization	
Mean Inpatient Visits in First 12 Months after Diagnosis	3 visits
Mean Outpatient Visits in First 12 Months after Diagnosis	18 visits

## Conclusion

- A significant proportion of allogeneic HCT patients develop cGVHD, and despite advances in the understanding of cGVHD, corticosteroids remain the mainstay of therapy.<sup>3</sup>
- Most cGVHD patients are not adequately managed with first-line corticosteroids, and many patients cycle through several therapies and have high HCRU.<sup>4</sup>
- Real-world utilization of systemic therapies is highly variable, particularly for patients who progress beyond the first LOT, which highlights the need for evidence-based innovative treatment approaches.
- cGVHD is a highly clinically and economically burdensome complication of allogeneic HCT, and safer, more effective treatments are needed as many patients are not currently well managed on available therapies.

## References

- Arai S, Arora M, Wang T, et al; Graft-vs-Host Disease Working Committee of the CIBMTR. Increasing incidence of chronic graft-versus-host disease in allogeneic transplantation: a report from the Center for International Blood and Marrow Transplant Research. *Biol Blood Marrow Transplant.* 2015;21(2):266-274.
- Lee, S.J., Vogelsang, G., and Flowers, M. Chronic graft-versus-host disease. *Biol Blood Marrow Transplant.* 2003; 9: 215-233.
- Flowers ME, Martin PJ. How we treat chronic graft-versus-host disease. *Blood.* 2015;125(4):606-615.
- Lee SJ, Nguyen TD, Onstad L, et al. Success of Immunosuppressive Treatments in Patients with Chronic Graft-versus-Host Disease. *Biol Blood Marrow Transplant.* 2018 Mar;24(3):555-562.

## Disclosures

CRB and MR are consultants, and SKA is employed by Kadmon Corporation, LLC at the time of research. KH, AM, and KF were employed by Trinity Life Sciences at the time of research. This study was funded by Kadmon Corporation, LLC.

