

REAL-WORLD TREATMENT PATTERN, ADHERENCE, COST, AND HEALTHCARE RESOURCE UTILIZATION OF COMMERCIALY-INSURED PATIENTS WITH WALDENSTRÖM MACROGLOBULINEMIA IN THE UNITED STATES

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INTRODUCTION

- Waldenström macroglobulinemia (WM) is a rare, incurable non-Hodgkin lymphoma
- There is limited real-world evidence on WM treatment utilization and associated economic outcomes in real-world patient populations

OBJECTIVE

- To evaluate the real-world treatment pattern, adherence, and economic outcomes in the commercially insured WM patient population in the United States (US)

METHODS

- Study design:** Retrospective, observational study
- Data source:** IBM MarketScan® commercial claims and Medicare supplement database
- Study population:**
 - Adult WM patients who were newly diagnosed and newly initiated treatment
 - The index date was defined as the date of the first administration or prescription of WM treatment
 - Inclusion criteria
 - Aged ≥18 years at index date
 - Continuous enrollment for ≥6 months before and ≥2 months following the first date of WM treatment
 - ≥2 diagnoses of WM (ICD-9-CM: 273.3 or ICD-10-CM: C88.0) on different days from April 1, 2014 to July 31, 2018
 - ≥1 WM treatment on or after the initial diagnosis date until July 31, 2018
 - No WM diagnosis or treatment before the initial diagnosis date
- Treatment regimen:**
 - Classified according to NCCN guidelines and identified using HCPCS and NDC codes
 - Treatment regimens for a given line of therapy were categorized based on the combination of all agents used within the first 60 days of WM treatment initiation
 - Five mutually exclusive categories of WM treatment regimen:
 - Rituximab monotherapy
 - Ibrutinib (monotherapy or in combination with rituximab)
 - Chemotherapy (monotherapy or in combination)
 - Proteasome inhibitor (monotherapy or in combination with rituximab)
 - Other regimens
- Treatment pattern:**
 - Evaluated by frequency and duration of treatment regimen
 - First-line therapy: defined as any WM treatment regimen observed ≤60 days after or on the index date until a new line of therapy
 - A new line of therapy was considered to be initiated when either one of the following events was observed:
 - The addition of or switch to a new WM treatment >60 days post-index date; or
 - A gap in therapy of >90 days followed by a restart of any WM treatment, including the index therapy
 - Lines of therapy are calculated for first-line (1L), second-line (2L), and third-line (3L)
- Adherence:**
 - Treatment duration:** The total number of days from the first day of a line of therapy to the last drug prescription date, plus derived days of supply for injectable drugs or days of supply for oral drugs of the respective line of therapy
 - Discontinuation:**
 - Defined as a treatment gap of more than 90 days from the last day of supply
 - Discontinuation was examined for each line of therapy, as well as overall, from the index date until the earliest date of death or study end date
 - Switching: Any new WM treatment >60 days after the start of a line of therapy
- Economic outcomes:**
 - Healthcare resource utilization: Frequency and duration of inpatient hospital admissions, outpatient visits, and pharmacy visits
 - Total costs: Calculated as the sum of inpatient, outpatient, and pharmacy costs per-patient-per-month (PPPM)

RESULTS

- Patient characteristics**
 - A total of 453 WM patients who were newly diagnosed and initiated therapy (mean age: 67 years, 51% male) were included in the study cohort (Table 1)
 - Patients were relatively evenly distributed geographically
 - Hypertension (42%) was the most common comorbidity, followed by gastroesophageal reflux disease (16%) and atrial fibrillation/cardiac arrhythmia (15%)

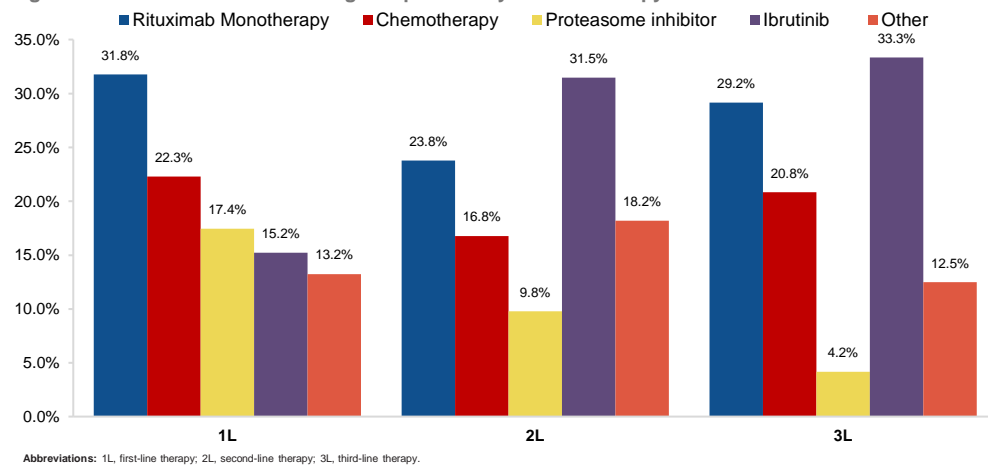
Table 1. Demographic and Clinical Characteristics of WM Patient Population

	WM Patients (N=453)
Age at index	
Mean (SD)	66.8 (12.2)
Median	64
Age group, n (%)	
18-34	3 (1)
35-54	60 (13)
55-64	166 (37)
65-74	85 (19)
75+	139 (31)
Sex	
Male	233 (51)
Female	141 (31)
Other/unknown sex	79 (17)
Geographic region, n (%)	
Northeast	81 (18)
North Central	108 (24)
South	124 (27)
West	60 (13)
Unknown	80 (18)
Charlson comorbidity index (CCI)	
Mean (SD)	1.1 (1.5)
Baseline comorbidity, n (%)	
Atrial fibrillation/arrhythmia (including all cardiac arrhythmias)	70 (15)
Cerebrovascular disease	50 (11)
Hypertension	190 (42)
Coronary artery disease (including myocardial infarction)	60 (13)
Renal disease (acute or chronic kidney disease/renal failure/dialysis)	56 (12)
Diabetes	58 (13)
Neutropenia	33 (7)
GERD	73 (16)
Headache	52 (11)
Hepatic disease	30 (7)
Duration of follow-up, days	
Mean (SD)	551.7 (392.9)
Median	447

Abbreviations: GERD, gastroesophageal reflux disease; SD, standard deviation; WM, Waldenström macroglobulinemia.

- Treatment patterns**
 - Among the total of 453 WM patients who received 1L therapy, 143 (32%) patients further received 2L therapy and 24 (5%) received 3L therapy
 - Rituximab monotherapy was the most commonly used 1L therapy (31.8%) while ibrutinib was the most commonly used regimen in both 2L (31.5%) and 3L (33.3%) therapies (Figure 1)

Figure 1. Treatment Patterns Among WM patients by Line of Therapy



- Adherence**
 - Treatment discontinuation rates were high in the overall population in each line of therapy (1L: 47.5% [mean duration: 246 days], 2L: 52.4% [mean duration: 231 days], 3L: 45.8% [mean duration: 212 days])
 - Discontinuation rates were generally highest for ibrutinib and rituximab, with 53.6% and 50.7% discontinuing in 1L therapy and 60.0% and 44.1% discontinuing in 2L therapy (Figure 2)
 - The overall treatment switching rate was highest in 1L (25.4%), followed by 10.5% in 2L and 20.8% in 3L therapies (Figure 3)

Figure 2. Treatment Discontinuation Rates: Overall and by Line of Therapy

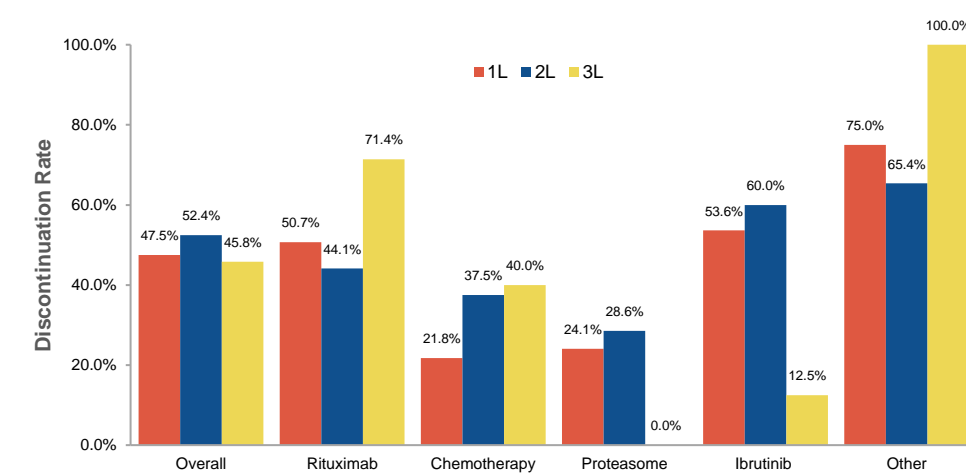
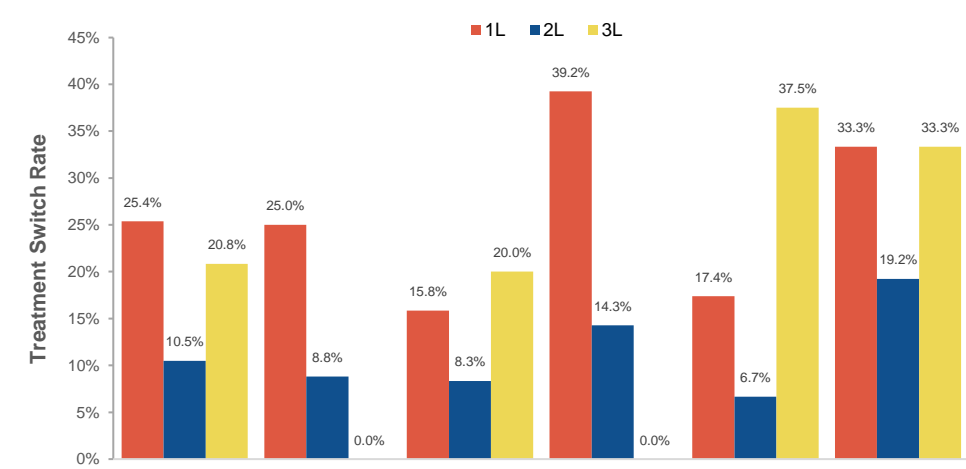


Figure 3. Treatment Switch Rates: Overall and by Line of Therapy

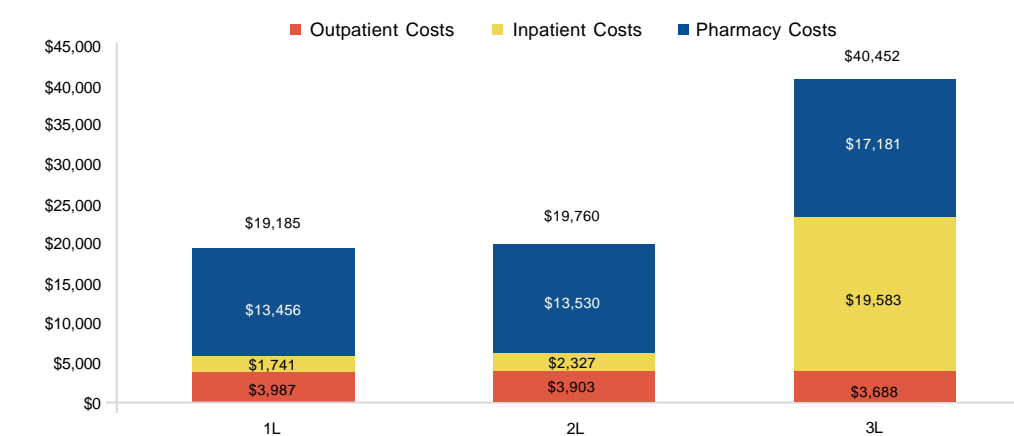


- Healthcare resource utilization and costs**
 - The overall hospitalization rate was 20% with an average length of stay (LOS) of 2.3 days
 - Approximately 17% (LOS: 1.4 days), 20% (LOS: 1.8 days), and 25% (LOS: 7.0 days) of patients had a hospitalization during the 1L, 2L, and 3L of therapy, respectively (Table 2)
 - The average total PPPM costs were \$19,819 in the overall WM population and increased by line of therapy (1L: \$19,185; 2L: \$19,760; 3L: \$40,452) (Figure 4)

Frequency (Per-Patient Per-Month)	Overall (N=453)	1L (n=453)	2L (n=143)	3L (n=24)
Outpatient visits				
Mean ± SD	4.73 ± 2.85	4.83 ± 2.85	4.68 ± 3.71	4.58 ± 2.75
ER visits				
Mean ± SD	0.1 ± 0.27	0.1 ± 0.28	0.06 ± 0.15	0.08 ± 0.12
Inpatient admissions				
Mean ± SD	0.05 ± 0.14	0.05 ± 0.15	0.06 ± 0.17	0.05 ± 0.13
Pharmacy visits				
Mean ± SD	4.01 ± 2.14	4.08 ± 2.17	3.85 ± 2.81	3.84 ± 1.99
Duration of hospitalization (Length of stay, days)				
Mean ± SD	2.29 ± 8.5	1.35 ± 4.33	1.8 ± 5.12	6.96 ± 26.43

Abbreviations: 1L, first-line therapy; 2L, second-line therapy; 3L, third-line therapy; SD, standard deviation; WM, Waldenström macroglobulinemia.

Figure 4. Total Healthcare Costs in WM Patients (PPPM)



DISCUSSION

- WM is rare and understudied, especially in real clinical practice
- This study evaluated the real-world utilization of treatment regimens by line of therapy in newly diagnosed WM patients in the US
 - Results reflected the variation of real-world treatment patterns from clinical treatment guidelines
- Study limitations were inherent to the use of claims databases in an observational study design and findings were subject to potential coding discrepancies entered for administrative processing
- Future studies are needed to further understand factors associated with treatment selection and outcomes

CONCLUSION

- There remains a significant clinical and economic burden with suboptimal treatment adherence in US commercially-insured patients with WM**

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This study was sponsored by BeiGene, Ltd. Logistic support was provided by Peloton Advantage, LLC, an OPEN Health company, and funded by BeiGene.

Presented at the AMCP Nexus 2021, Denver, Colorado, October 18–21, 2021