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Patient Characteristics and Treatment Patterns of US Medicare Fee-For-Service Beneficiaries with Waldenström Macroglobulinemia

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OBJECTIVE

To describe patient characteristics and treatment patterns of single-agent ibrutinib or rituximab in the first-line (1L) setting among Medicare Fee-for-Service (FFS) beneficiaries

CONCLUSIONS

This real-world evidence suggests a significantly longer time to next treatment among older adults with WM initiating 1L treatment with single-agent ibrutinib, compared with 1L rituximab, consistent with existing clinical observations

While total healthcare costs were similar between cohorts, treatment with ibrutinib was associated with lower hospitalization and outpatient visits costs compared with rituximab treatment

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INTRODUCTION

- Waldenström macroglobulinemia (WM) is an indolent form of non-Hodgkin lymphoma (NHL) and is most commonly diagnosed in older adults[1]
- Current treatments for WM include combinations of chemotherapy and monoclonal antibodies; targeted agents including Bruton tyrosine kinase (BTK) inhibitors (ibrutinib, zanubrutinib) play a significant role in treating WM[2]
- Despite its modest efficacy, single-agent rituximab is the most frequently prescribed first-line (1L) treatment for symptom control in older adults with WM[3]
- In clinical trials, 1L single-agent ibrutinib yielded durable clinical outcomes and was well tolerated by older or frail patients[4,5]
- However, real-world evidence differentiating treatment outcomes of ibrutinib and rituximab in older adults with WM remains scant

METHODS

- Data were obtained from Center's for Medicare & Medicaid Services (CMS)-sourced 100% Medicare FFS files, with Part A and Part B medical encounters (inpatient and outpatient care, respectively) and Part D prescription drug events

Outcomes

- Patient demographics, assessed on the index date, and clinical characteristics, assessed during the 12-month baseline period
- Time to next treatment (TTNT), defined as the interval between initiation of 1L treatment and start of the next treatment, or the date of death prior to next treatment
  - Next treatment included any change in or addition to treatment >90 days after 1L treatment initiation
- Healthcare utilization and direct costs
  - All-cause and WM-related healthcare resource use and cost was reported in the service categories of physician office, emergency room, durable medical equipment, supportive care, inpatient hospital, and pharmacy in the baseline period and during 1L treatment
    - WM-related costs were defined as a medical encounter in any setting of care with a qualifying diagnosis code of WM during any step of the claim processing
  - Utilization and costs were reported as per-patient-per-month (PPPM)
- Summary of total medical (inpatient hospital, emergency department visit, physician office visit, other carrier service, and institutional outpatient visit costs) and total healthcare costs (total medical and Part D pharmacy)
  - All costs were adjusted to 2022 US dollars using the medical care component of the Consumer Price Index obtained from the US Bureau of Labor Statistics

Analyses

- Baseline characteristics were reported using descriptive statistics
- TTNT was compared using univariate Cox proportional hazards models

Sample Selection and Attrition

Inclusion criterion 1: Adult patients aged ≥18 years with ≥2 medical claims of WM and ≥1 medical or pharmacy claim of NCCN-referenced treatment for WM between Jan 1, 2014 and Dec 31, 2019; index date is defined as the date of the first qualifying treatment
N=12,598

↓

Inclusion criterion 2: ≥12 months of continuous enrollment in Medicare Part A, B, and D both before (baseline period) and after (follow-up period) the index date
N=7299

↓

Exclusion criterion 1: any claims for other types of cancer (i.e. breast, prostate, kidney) or bleeding disorders, evidence of previous NCCN-treatment during the baseline period, or evidence of enrollment in a clinical trial during the study period
N=5041

↓

Exclusion criterion 2: evidence of chronic lymphocytic leukemia, mantle cell lymphoma, follicular lymphoma or marginal zone lymphoma, or receipt of treatment for any of these cancers during the study period
N=4584

↓

Rituximab: received 1L single-agent rituximab
N=1871

Ibrutinib: received 1L single-agent ibrutinib
N=783

NCCN, National Comprehensive Cancer Network.

RESULTS

- Of 4584 patients diagnosed with WM who initiated an NCCN-referenced treatment regimen, 1871 patients (41%) initiated single-agent rituximab and 783 patients (17%) initiated single-agent ibrutinib
- The remaining 1930 patients (42%) received a combination of other treatments including, but not limited to, rituximab in combination with bendamustine (773 patients [17%]), chemotherapies (563 patients [12%]), or ibrutinib + rituximab (90 patients [2%])

Patient Demographics and Clinical Characteristics Were Generally Similar Between Rituximab and Ibrutinib Cohorts

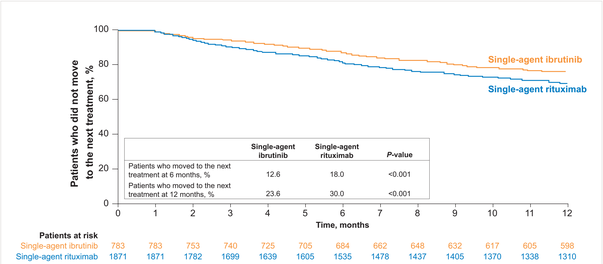
	Rituximab N=1871	Ibrutinib N=783
Age, mean ± SD, years	77 ± 8	77 ± 8
Age group, n (%)		
18-64	48 (3)	25 (3)
65-69	250 (13)	110 (14)
70-74	416 (22)	157 (20)
75-79	447 (24)	179 (23)
80-84	367 (20)	156 (20)
85+	343 (18)	156 (20)
Sex, n (%)		
Female	924 (49)	327 (42)
Male	947 (51)	456 (58)
Race or ethnicity, n (%)		
White	1719 (92)	707 (90)
Black or African American	45 (2)	22 (3)
Hispanic or Latino	34 (2)	18 (2)
Asian	27 (1)	11 (1)
Other	20 (1)	11 (1)
Unknown	26 (1)	14 (2)
Census region, n (%)		
Northeast	414 (22)	220 (28)
Midwest	447 (24)	146 (19)
South	613 (33)	219 (28)
West	396 (21)	196 (25)
US territory/unknown	<11 (NA)[a]	<11 (NA)[a]
Index year, n (%)		
2014	369 (20)	48 (6)
2015	334 (18)	152 (19)
2016	334 (18)	162 (21)
2017	308 (17)	157 (20)
2018	256 (14)	148 (19)
2019	270 (14)	116 (15)
CCI score, mean ± SD	4.5 ± 2.6	4.6 ± 2.7
CCI score, n (%)		
CCI 0-5	1350 (72)	577 (74)
CCI 6-10	456 (24)	176 (23)
CCI 11+	65 (4)	30 (4)
Baseline comorbidities, n (%)		
Stroke	85 (5)	39 (5)
Myocardial infarction	47 (3)	12 (2)
Hypertension	1353 (72)	531 (68)
Atrial fibrillation	316 (17)	137 (18)
Other cardiovascular conditions[b]	609 (33)	241 (31)
Renal dysfunction	233 (13)	93 (12)
Major bleeding events requiring hospitalization[c]	85 (5)	38 (5)
Infection requiring hospitalization[d]	144 (8)	69 (9)
Time from first observed diagnosis in study period to index treatment, mean ± SD, days	367 ± 495	510 ± 533
12-month baseline all-cause healthcare costs, mean ± SD, USD	2461 ± 3425	2583 ± 3372

CCI, Charlson Comorbidity Index; NA, not applicable; SD, standard deviation.
[a]Categories with <11 patients were masked to ensure patient confidentiality.
[b]Other cardiovascular conditions include atrial flutter, cardiovascular event (transient ischemic attack, ischemic stroke including cerebrovascular accidents and cerebral ischemia, cardiac arrhythmias including atrial fibrillation and atrial flutter, and cardiac failure), congestive heart failure, peripheral vascular disease, pulmonary circulation disorders, stroke, valvular disease, and ventricular arrhythmias.
[c]Major bleeding events include gastrointestinal bleeding, intracranial bleeding, bleeding complication of a procedure, other bleeding, hematuria, and hemoptysis.
[d]Infections include pneumonia, meningitis/encephalitis, bacteremia/sepsis, cellulitis/soft-tissue infections, endocarditis, pyelonephritis, and septic arthritis/osteomyelitis.

Time to Next Treatment

- Mean ± SD duration of 1L treatment was 94 ± 97 days with single-agent rituximab and 220 ± 1467 days with single-agent ibrutinib
- After controlling for baseline characteristics, patients treated with ibrutinib were 23% less likely to move to next treatment than patients treated with rituximab (*P*=0.003).

TTNT Was Significantly Longer For Patients Treated With 1L Ibrutinib Than For Those Treated With 1L Rituximab



Healthcare Utilization and Direct Costs

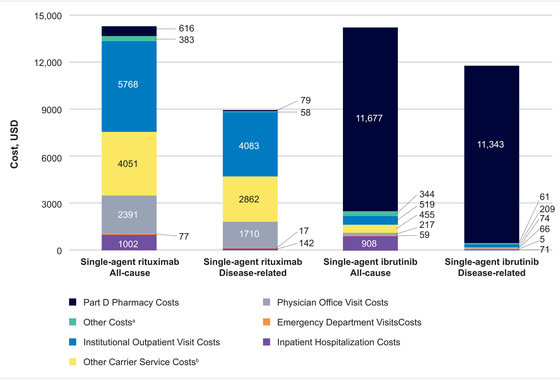
PPPM Healthcare Resource Utilization Differed Between 1L Ibrutinib and Rituximab Treatments

	Rituximab N=1871		Ibrutinib N=783	
	All-cause	WM-specific	All-cause	WM-specific
All-cause inpatient hospitalizations, %	13	2	26	2
Hospital length of stay, mean ± SD, days	3.0 ± 2.8	4.2 ± 3.9	1.4 ± 1.6	1.7 ± 2.2
All-cause 30-day readmission rate,[a] %	15	NA[b]	15	NA[b]
Emergency department visits , %	14	1	26	3
Outpatient visits, %	72	50	79	58
Physician office visits, %	88	61	91	69
Post-acute care stays, %	8	1	15	2
Number of unique medications, mean ± SD	2.9 ± 1.6	0.2 ± 0.0	1.4 ± 1.0	0.1 ± 0.0

[a]30-day readmission rates among those with an inpatient hospitalization during the period of 1L treatment.
[b]Categories with <11 patients were masked to ensure patient confidentiality.

- A higher proportion of ibrutinib-treated patients than rituximab-treated patients were hospitalized (26% vs 13%, *P*<0.001), however the hospital stays were longer for rituximab-treated patients than for ibrutinib-treated patients (3.0 vs 1.4 days, *P*<0.001)
- Total direct healthcare costs through the 1L follow-up period were similar between cohorts (*P*=0.310)
  - Rituximab: mean ± SD, $14,287 ± $12,077; median, $10,781
  - Ibrutinib: mean ± SD, $14,179 ± $10,224; median $12,283
- Overall, 64% of total all-cause healthcare costs were attributed to institutional outpatient visits, physician office visits, and inpatient hospitalization visits in rituximab-treated patients, while 82% of the total all-cause healthcare costs in ibrutinib-treated patients were Part D pharmacy costs
  - Similar trends were seen for WM-specific healthcare costs

PPPM Healthcare Costs by Setting of Care Differed Between 1L Ibrutinib and Rituximab Treatments



[a]Other, minor costs including durable medical equipment and post-acute care costs.
[b]Costs for claims submitted by medical professionals that were not categorized as physician office visit.

Limitations

- Claims data are provided mainly for billing and reimbursement purposes, thus data capturing medical conditions and outcomes may not be fully documented
- For identifying treatments, Medicare claims capture physician-administered and self-administered treatments; any information on utilization of medication during a hospitalization or purchased over the counter is not captured in the data. Additionally, medications used in clinical trials are not captured in the Medicare claims.
- This study cannot be used to determine causality, as claims data only capture those disease entities and variables that have their own specific billing codes.
- This retrospective cohort study cannot be generalized to all population as it excludes the patients with limited access to the health care system, uninsured, or those insured outside the Medicare FFS system

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