Treatment Regimens and Duration of Lines of Therapy in Medicare-Enrolled Patients With Multiple Myeloma

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INTRODUCTION

- In 2013, it was estimated that 95,688 people were living with multiple myeloma (MM) in the United States.[1]
- There has been significant improvement in the prognosis of MM patients over the last decade, largely due to the availability of novel therapies.[2]
- There is now availability of numerous chemotherapeutic options for MM treatment and these agents are very often used as combination regimens.
- Not surprisingly, many patients receive multiple lines of therapy, as relapse and resistance to previous treatments occur.[3,4]
- In this study, we sought to describe the use of drug regimens by lines of therapy and to describe the duration of line of therapy in Medicare-enrolled MM patients.

METHODS

- Data were ascertained from the Centers for Medicare & Medicaid Services (CMS) 100% Hematologic Cancer File.
- Included Medicare beneficiaries:
  - Diagnosis of MM (using a combination of the International Classification of Diseases, Revision 9 [ICD-9] codes 203.0X and diagnosis tests or treatment) between January 1, 2008 and December 31, 2011. MM case identification was done using a validated algorithm and the diagnosis date was identified as the disease index date.
  - Initiated treatment with a chemotherapeutic agent specific to MM following the disease index date. The date of treatment initiation was identified as the treatment index date.
  - Continuously enrolled in Medicare Part A, Part B, and Part D between treatment index date and 12 months prior to the disease index date.
  - Aged 18 years or older at the disease index date.
- Excluded patients:
  - Received chemotherapy and/or radiotherapy in the 12 months before the disease index date.
  - Had evidence of bone marrow transplant or stem cell transplant in the 12 months prior to the disease index date.
- Patients receiving treatments were identified for multiple lines of therapies from induction therapy through the fourth line.
  - Treatment regimens within lines were identified using claims for medications within 90 days of the start of the line.
  - Medications were identified from Medicare Part D prescription drug event claims (using NDC codes) and Part B line items and Part A outpatient claims (using HCPCS codes).
  - Drug regimens were based on National Comprehensive Cancer Network MM treatment guidelines.
  - Drug regimens included proteasome inhibitor (PI): bortezomib; immunomodulatory agents (IMiD): lenalidomide, thalidomide; PI/IMiD combinations; and other chemotherapies.
  - To further identify patients who initiated multiple lines of therapy, we require them to be continuously enrolled in Medicare Parts A, B, and D between the dates of treatment initiation for the current and previous lines.
  - Patients advanced lines of therapy after a 90-day gap in all treatments (break) or when a drug was added to a regimen after 90 days (direct switch).
- Patient characteristics for each line of therapy (including age, sex, race, geographic region, calendar year, and comorbidity) were described using descriptive statistics.
- Duration of treatment (overall and by regimen) for each line of therapy was reported.

RESULTS

- A total of 15,474 Medicare beneficiaries diagnosed with MM and treated with a first-line therapy were included in this analysis; the patient flow through the inclusion criteria is shown in **Figure 1**.
- Demographic and clinical characteristics for patients included in lines 1 through 4 are shown in **Table 1**.
  - 15,474, 8,308, 3,878, and 1,608 MM patients initiated first-, second-, third-, and fourth-line treatments, respectively.
  - For patients included who were treated with first-line therapy, mean (standard deviation) age (defined at disease index date) was 75.1 (8.8) years; 54.4% were female and 77.5% were white.
  - The mean age (defined at disease index date) of included patients decreased progressively from line 1 to line 4.

Figure 1. Multiple myeloma (MM) patient flow through the study inclusion criteria

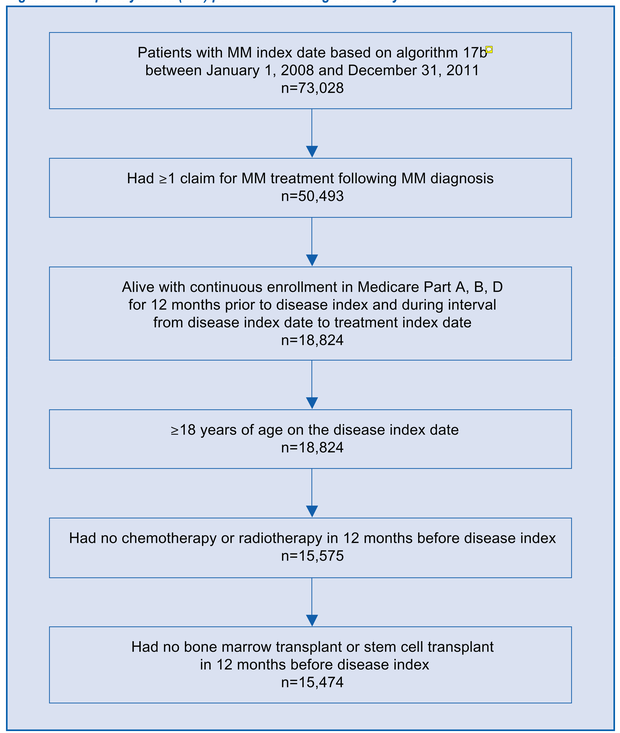

Table 1. Demographic characteristics of study population

	Line 1 cohort	Line 2 cohort	Line 3 cohort	Line 4 cohort
N	15,474	8,308	3,878	1,608
Age mean (SD), years*	75.1 (8.8)	74.2 (8.5)	73.3 (8.2)	72.6 (8.3)
Age, %*				
18–64	8.6	9.2	9.5	10.3
65–74	40.0	44.4	49.2	50.9
75+	51.4	46.4	41.3	38.7
Sex, %				
Male	45.6	46.6	47.1	46.1
Female	54.4	53.4	52.9	53.9
Race, %				
White	77.5	78.5	80.2	80.0
Black	16.3	15.4	14.1	14.2
Other	6.1	6.2	5.8	5.8
Index year				
2008	21.0	6.5	0.9	*
2009	24.0	19.0	11.1	4.0
2010	24.3	24.6	23.8	19.0
2011	25.6	26.9	30.3	35.3
2012	5.1	23.0	33.9	41.7
Charlson comorbidty index				
0	18.2	2.1	2.1	2.1
1–3	56.3	62.1	64.6	62.9
4+	25.5	35.7	33.3	35.0
Selected comorbid conditions				
Congestive heart failure	17.4	21.2	22.7	24.6
Diabetes	27.6	29.9	31.1	31.2
COPD	18.9	23.5	26.9	30.5
Chronic kidney disease	35.9	41.8	45.4	48.2
Anemia	58.8	72.9	79.4	82.8
Osteoporosis	12.1	15.0	17.0	19.0
Neutropenia	1.6	7.3	13.7	17.4
Thrombocytopenia	6.8	13.5	19.2	22.6
Peripheral neuropathy	5.1	14.7	22.2	26.5

*Age as at MM disease index date.
COPD, chronic obstructive pulmonary disease; MM, multiple myeloma; SD, standard deviation.

- Regimen distribution is shown in **Table 2**.
  - 30%, 29%, 10%, and 31% of patients were treated with PI, IMiD, PI/IMiD combinations, and other chemotherapies, respectively, as line 1 regimens.
  - Regimen distributions were similar for lines 1 through 4.
- Duration of treatment regimens is shown in **Table 3**.
  - Overall, the mean duration of line of therapies 1 through 4 was 386, 329, 268, and 232 days, respectively; while the corresponding median durations were 284, 241, 199, and 177 days, respectively.
  - For lines 1 through 4, patients treated with IMiDs had the longest treatment duration.

Table 2. Regimen distributions across lines of therapy

	Line 1	Line 2	Line 3	Line 4
Overall, n	15,474	8,308	3,878	1,608
Regimen, n (%)				
Bortezomib based	4,693 (30.3)	1,999 (24.1)	924 (23.8)	378 (23.5)
Lenalidomide based	3,199 (20.7)	2,029 (24.4)	954 (24.6)	365 (22.7)
Thalidomide based	1,289 (8.3)	464 (5.6)	181 (4.7)	81 (5.0)
Bortezomib lenalidomide combo	1,228 (7.9)	788 (9.5)	398 (10.3)	156 (9.7)
Bortezomib thalidomide combo	318 (2.1)	183 (2.2)	84 (2.2)	38 (2.4)
Other	4,747 (30.7)	2,845 (34.2)	1,337 (34.5)	590 (36.7)

Table 3. Regimen durations

	Line 1	Line 2	Line 3	Line 4
Regimen duration in days, mean (SD)	15,474	8,308	3,878	1,608
Overall	386 (332)	329 (280)	268 (230)	232 (194)
Bortezomib based	362 (304)	308 (260)	237 (194)	222 (168)
IMiD	426 (322)	366 (274)	316 (231)	265 (204)
Lenalidomide based	424 (353)	364 (290)	323 (263)	268 (229)
Thalidomide based	432 (380)	377 (333)	279 (255)	254 (231)
Bortezomib/IMiD	416 (343)	333 (247)	276 (206)	246 (189)
Bortezomib/lenalidomide combo	425 (298)	331 (268)	284 (235)	246 (158)
Bortezomib/thalidomide combo	384 (328)	341 (291)	241 (180)	247 (225)
Other	360 (333)	309 (275)	245 (217)	209 (185)

IMiD, immunomodulatory agents; SD, standard deviation.

LIMITATIONS

- The MM case identification algorithm used in this study was not validated using Medicare data. Thus, its performance in the Medicare population is unknown.
- Some Medicare Part D enrollees without low-income subsidy status who reach the coverage gap may choose to obtain their medications from a non-Part D source and would likely either have been misclassified as non-treated or have a misclassified treatment regimen.

CONCLUSIONS

- In the Medicare MM population, the distribution of treatment regimens including PI, IMiD, and other chemotherapies were similar across lines 1 through 4.
- The treatment duration of lines of therapy decreased from line 1 to 4.
- These data provide insights into real-world use of MM treatments.

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CONFLICT OF INTEREST DISCLOSURES

Dr. Yusuf and Ms. Natwick report no conflicts of interest. Ms. Felici was an employee of Onyx Pharmaceuticals, Inc., an Amgen subsidiary, South San Francisco, CA. Dr. Werther is an employee of Amgen, Inc.

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