

Comorbidity and Disability in Medicare Beneficiaries Newly Diagnosed with Moderate to Severe Indolent Systemic Mastocytosis

Allison A. Petrilla¹, Erin Sullivan², Maria Roche², Jenna Cohen², Chelsea Norregaard², Uyen Nguyen², Chris Sloan², Alison R. Silverstein¹, Anne Murunga¹, Jill Schinkel¹

¹Avalere Health, Washington DC, USA; ²Blueprint Medicines, Cambridge, MA, USA

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Introduction & Objective

- Non-advanced systemic mastocytosis (non-AdvSM), including indolent SM (ISM), is a rare, clonal mast cell neoplasm primarily driven by the *KIT D816V* mutation. Mast cells infiltrate and accumulate in various tissues and organ systems.^{1,2} Uncontrolled proliferation and activation of mast cells results in severe and often unpredictable symptoms including skin lesions, anaphylaxis, and gastrointestinal involvement. SM is difficult to diagnose, and patients may experience misdiagnosis or delayed diagnosis before confirmation by a specialist.
- This study describes the characteristics and comorbidity profile of Medicare Fee for Service (FFS) beneficiaries newly diagnosed with moderate to severe ISM, including those qualifying for Medicare due to non-age-related factors.

Methods

- Medicare FFS beneficiaries with ISM were identified using Centers for Medicare and Medicaid Services-sourced 100% Medicare FFS claims (Parts A/B/D) and enrolment data.
- Newly diagnosed moderate to severe ISM patients³ were identified as having (1) ≥ 2 medical claims with diagnosis of SM (ICD-10-CM D47.02, C94.30-.32, or C96.21) between January 1, 2017 and December 31, 2018, and (2) prescribed tyrosine kinase inhibitors or antihistamines OR had a diagnosis of anaphylaxis, splenomegaly, hepatomegaly, or bone fracture, (3) no prior SM diagnosis in the 12-month baseline period, and (4) without evidence of advanced SM (AdvSM); >2 medical claims with diagnosis of aggressive SM, SM with associated hematological neoplasm [SM-AHN], or mast cell leukemia).

- The index date was the date of first observed SM diagnosis. Continuous enrolment in Medicare Parts A/B/D for 12 months pre- and post-index was required.
- Demographic characteristics, presence of comorbid conditions, and use of physician services and medications during the 12-month pre-diagnosis period were reported for all ISM beneficiaries and for the subgroup who qualified for Medicare based on non-age-related factors (i.e., due to end stage renal disease [ESRD] or a pre-existing disability).

Results

Demographic Characteristics

- A total of 333 Medicare beneficiaries with ISM were identified, 88 (26%) of whom qualified for Medicare due to non-age-related factors. The majority who qualified with non-age-related factors had an undisclosed pre-existing disability and <11 qualified due to ESRD.
- Mean age of the study cohort was 67 years (mean age of 51 years for the subgroup that qualified for Medicare due to non-age-related factors). Approximately three-quarters of study patients were female (**Table 1**).
- 19% of the study cohort was dual eligible for Medicare and Medicaid and 23% were eligible to receive the Medicare Part D Low Income Subsidy (53% and 64%, respectively, within the subgroup that qualified for Medicare due to non-age-related factors) (**Table 1**).

Table 1: Beneficiary Demographic Characteristics at Index

Baseline Characteristics	ISM Cohort (N = 333)		ISM Subgroup - Qualified for Medicare Due to Non-Age-Related Factors (N = 88)	
	N	%	N	%
Patient Age in Years, Mean (SD)	67.3	11.7	51.1	8.7
Sex				
Male	80	24.0%	22	25.0%
Female	253	76.0%	66	75.0%
Race				
White	312	93.7%		
Non-white	21	6.3%	<11	
US Census Region				
Northeast	73	21.9%	21	23.9%
Midwest	73	21.9%	20	22.7%
South	95	28.5%	23	26.1%
West/Other/Unknown	92	27.6%	24	26.3%
Dual Eligible for Medicare and Medicaid				
No	269	80.8%	41	46.6%
Yes	64	19.2%	47	53.4%
Part D Low Income Subsidy				
No	257	77.2%	32	36.4%
Full or Partial	76	22.8%	56	64.0%
Index Year				
2017	149	44.7%	47	53.4%
2018	184	55.3%	41	46.6%

Physician Visits, Comorbidities, and Prescription Medications in the 12 Months Prior to Diagnosis of ISM

- During the 12 months prior to diagnosis, the full ISM cohort had mean (SD) 15.3 (14.7) specialty physician visits per person and the subgroup that qualified for Medicare due to non-age-related factors had 13.0 (15.0) specialty visits per person. Mean primary care physician visits were approximately 4 per person across the both the full ISM and the subgroup.
- Hypertension and malignancy were the most observed comorbid conditions in the full ISM cohort (**Figure 1**). Other tumor types and the tumor types in the ISM subgroup were not reportable due to <11 sample sizes.
- Observed prevalence of comorbidities among the ISM patients that qualified for Medicare due to non-age-related factors were higher than among the full ISM cohort for select mental health conditions (anxiety: 43% vs. 29%; depression 38% vs. 27%), pulmonary diagnoses (asthma 43% vs. 29%; chronic obstructive pulmonary disease [COPD] 51% vs. 36%), and migraine (27% vs. 11%).

Figure 1: Frequently Observed Comorbidities in the 12 Months Prior to ISM Diagnosis

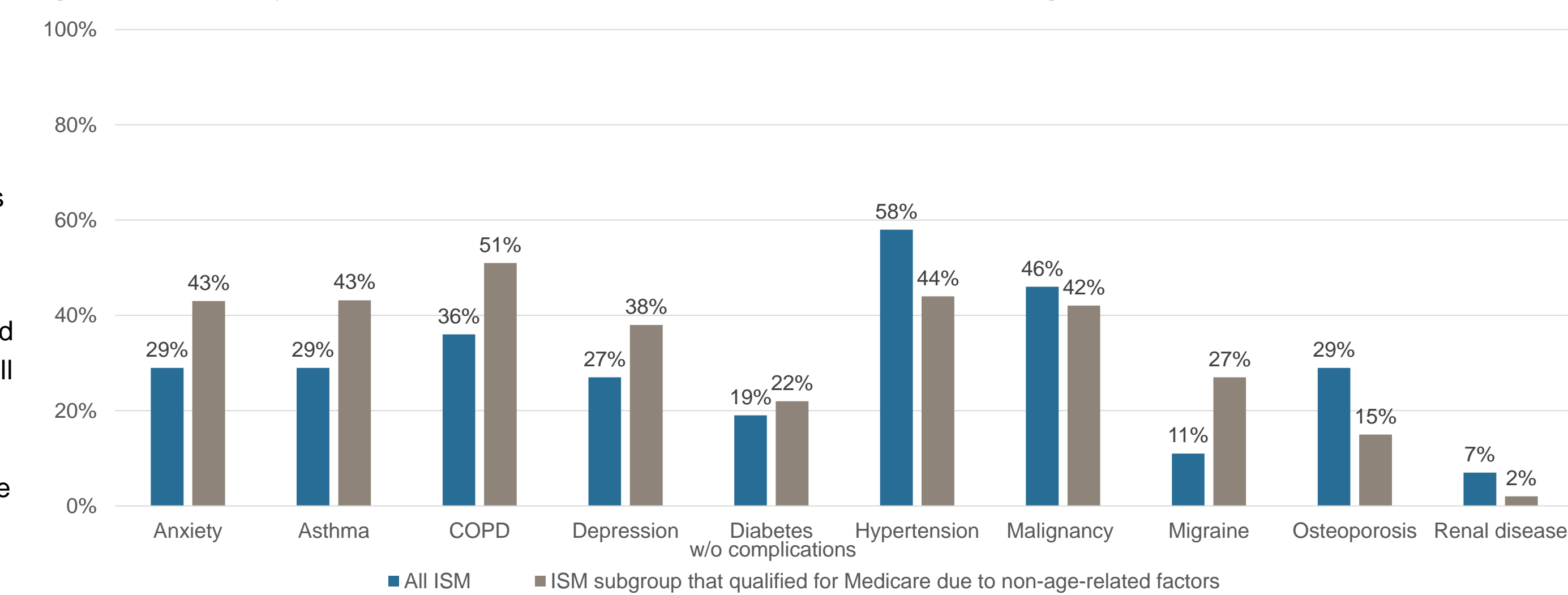
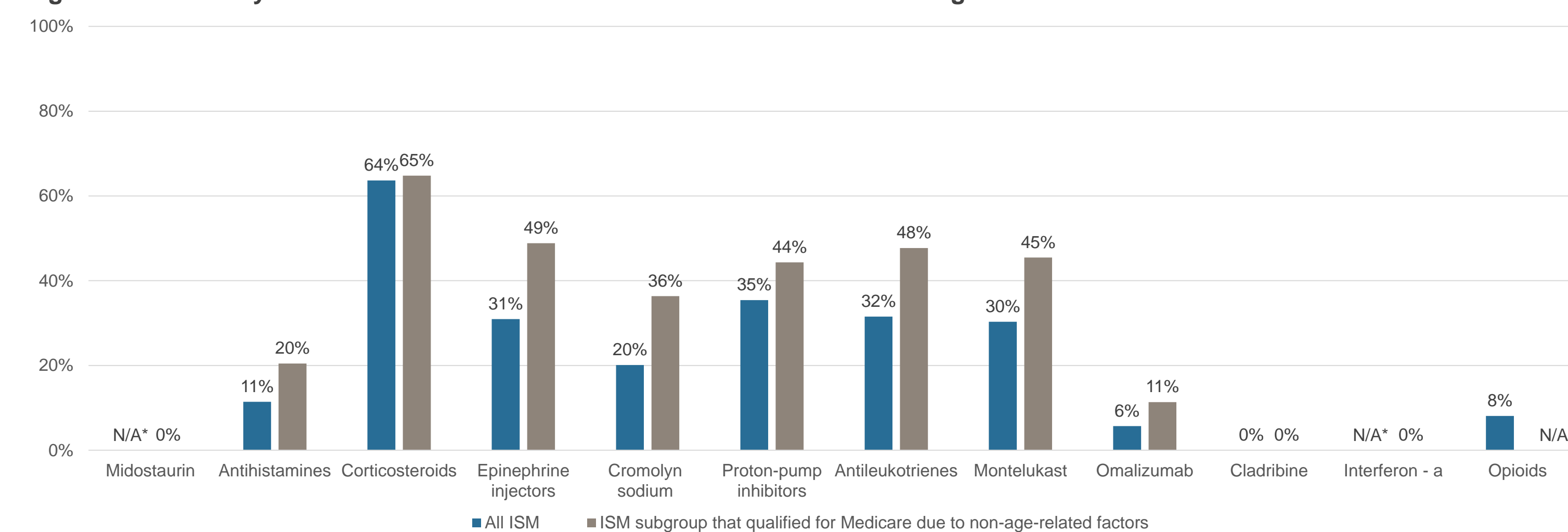


Figure 2: Commonly Prescribed Medications in the 12 Months Prior to ISM Diagnosis



* <11 ISM patients received this treatment.

**Opioid use in ISM subgroup that qualified for Medicare due to non-age-related factors was not evaluated.

Limitations

- Medicare beneficiaries with SM were identified beginning January 1, 2017, however, the ICD-10 diagnosis code for SM (D47.02) was not available until October 1, 2017.
- The study cohort was limited to those with no evidence of SM in the 12 months prior to index, but patients may have been initially diagnosed before this period. Additionally, because SM is difficult to diagnose, the identification criteria used may not have captured all ISM patients. Over 90% of ISM patients with malignancy had evidence of mast cell neoplasm, but these patients did not meet the full exclusionary criteria for SM-AHN.
- Future research may consider refining the algorithm to identify patients who likely have ISM but are not yet diagnosed and to delineate between patients with ISM, smoldering SM, and AdvSM diagnoses.

Conclusions

- In this real-world study, 26% of Medicare beneficiaries with newly diagnosed ISM qualified for Medicare due to non-age-related factors, compared to 14% in all of Medicare.
- The rate of dual eligibility for Medicare/Medicaid and receipt of partial or full Part D subsidy in the ISM subgroup that qualified for Medicare due to non-age-related factors was substantially higher than the full ISM cohort.
- In the 12 months prior to SM diagnosis, ISM patients had high rates of specialty physician visits and were prescribed an average of nearly 12 different medications. The comorbidities of the ISM cohort that qualified for Medicare due to non-age-related factors appeared different from those of the full ISM cohort, with mental health diagnoses, pulmonary-related conditions, and migraine observed in more patients.
- Reason for any underlying disability was not captured in the data and therefore, the comorbidity profile of ISM patients may be underestimated in this study. A more detailed understanding of specialty physician referrals and visits and comorbidities experienced prior to SM diagnosis may have implications for earlier SM diagnosis.
- Comorbidity burden and the reason for Medicare eligibility may impact beneficiaries' ability to work or perform activities of daily living. Further research on the relatively high proportion of ISM patients enrolled in Medicare based on non-age-related criteria is warranted.

References

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