Patient Cost Sharing and Receipt of Erythropoiesis-Stimulating Agents Through Medicare Part D

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Abstract

Purpose: Medicare Part D prescription benefits cover injected medications, normally covered under Part B, when administered outside of physician offices. Erythropoiesis-stimulating agents (ESAs) used for chronic anemia management in patients with myelodysplastic syndromes (MDS) are commonly injected in a physician office but can be administered safely at home. In this study, we explored out-of-pocket (OOP) costs and receipt of Part D–covered ESAs in Medicare beneficiaries with MDS.

Materials and Methods: Patients with MDS enrolled in Medicare Parts A, B, and D were identified using diagnosis codes from 100% claims from 2006 to 2008. OOP costs for the mean erythropoietin alfa claim were compared for Parts B and D. Multivariable models examined the effect of low-income subsidy

(LIS) and other Part D cost sharing on receipt of any ESA and any Part D–covered ESA.

Results: A total of 13,117 (62.9%) of 20,848 patients received ESAs, but only 1,436 (6.9%) had any Part D claim. OOP payment was \$348 under Part D versus \$161 under Part B. Among patients with ESA use, those with LIS were 4× more likely to receive Part D ESAs ($P < .01$).

Conclusion: Few patients with MDS received ESAs through Part D. OOP payments required under Part D were substantially higher than under Part B. Cost sharing, as reflected by LIS receipt, likely affected decisions to prescribe ESAs outside of the physician office. Improved coordination between Part B and D benefits regarding issues of home injection of medications may create incentives that improve patient access and convenience and reduce costs associated with administration.

Introduction

The Medicare Part B benefit covers injected medications when they are administered in conjunction with a physician office visit.¹ Some medications are physician administered because of potential acute adverse events, the need for precise dosing or injection placement, or potential drug-handling risks. The requirement to visit a physician to receive therapy may create physical barriers for persons with mobility limitations and generates time, travel, and additional out-of-pocket (OOP) visit costs, particularly with chronic use, creating access issues for patients who might benefit from therapy. Some Part B–covered injected medications may be administered safely outside of the physician office,² and implementation of the Part D prescription drug benefit in 2006 provided the mechanism for Medicare coverage.^{3,4} Little is known about the extent to which this occurs or about what Part D plan- or patient-level factors influence this choice.

A key feature of the Part D benefit is variation in cost sharing across plans and over the course of the coverage year. The standard Part D benefit includes a deductible phase, an initial coverage phase with 25% coinsurance, a coverage gap (100% patient contribution), and a catastrophic phase, with patients responsible for a relatively small copayment or 5% of the prescription cost. In 2013, the cumulative total spending thresholds were \$325, \$2,970, and \$4,750 for the initial coverage,

coverage gap, and catastrophic phases, respectively.⁵ Actuarially equivalent and basic alternative plans use tiered formularies with differential copayment amounts, depending on whether the drugs are generic or brand or are designated as preferred. Enhanced alternative plans have additional benefits such as reduced cost sharing in the coverage gap but charge higher premiums. Nonstandard plans commonly have three or four tiers, although variants may have as many as six. Specialty tiers, which apply coinsurance rates of up to 33% to high-cost medications, have been permitted since 2007.⁶ Beneficiaries with incomes < 135% of the federal poverty guidelines and limited assets can receive additional assistance for Part D premiums and cost sharing through the low-income subsidy (LIS) program.⁷ For Medicare beneficiaries enrolled in Part D and receiving full LIS, cost sharing was limited to \$6.60 per brand prescription fill in 2013, and there was \$0 in cost sharing in the catastrophic phase or for nursing home residents.

In this study, we examined use of erythropoiesis-stimulating agents (ESAs) to manage anemia in patients with myelodysplastic syndromes (MDS). MDS are a group of hematopoietic stem-cell neoplasms characterized by ineffective hematopoiesis, with resultant cytopenias. Approximately 80% of patients with MDS have symptomatic anemia, and management of anemia is a key therapeutic challenge.⁸ Supportive care commonly includes ESAs, which are used by two thirds of patients with

MDS at some point in their disease course.⁹ Erythropoietin alfa, approved by the US Food and Drug Administration for use in patients with cancer with chemotherapy-induced anemia, is generally administered through subcutaneous injection to those with MDS in physician offices, at 40 to 60,000 units from one to three times per week.¹⁰ Darbepoetin, a longer-acting form, is administered every 1 to 3 weeks.¹⁰ ESAs have been covered by Medicare Part B for > 20 years. As with selected other injected medications, many patients could benefit from the option of home injection,² but Part D plans commonly assign substantial copayments associated with nonpreferred brand drugs or even specialty tiers and commonly use prior authorization for expensive drugs. As a result, Part D plans may place greater barriers on ESA coverage relative to Part B. In this analysis, we examined source of coverage for ESAs in a Part D-enrolled cohort of Medicare beneficiaries with MDS and described OOP requirements under Part D relative to Part B. We examined the relationship between both Part D cost-sharing requirements and selected patient characteristics and receipt of ESAs outside of the physician office setting.

Materials and Methods

Data and Cohort Selection

We used a unique database of Medicare beneficiaries with MDS generated from 100% of Medicare enrollment and claims files from 2005 through 2008. The enrollment files included monthly indicators of participation in Medicare Parts A, B, C (Medicare Advantage), and D, as well as selected demographic characteristics. Medicare claims included detailed information on dates; services provided based on International Classification of Diseases (ninth revision) Clinical Modification procedure codes, Healthcare Common Procedure Diagnosis Coding System codes, and/or National Drug Codes; diagnoses; Medicare reimbursement; patient liability; and indicators for whether the claim was subject to prior authorization, step therapy, or quantity limits. Enrollment and claims data were supplemented with Part D plan characteristics, zip code-level demographic measures from the 2000 US Census, and a measure of urbanicity.^{11,12}

Inclusion in the cohort of patients with MDS required one inpatient claim with an MDS diagnosis (238.7 before October 2006; 239.72 to 239.75 beginning October 2006) or two outpatient claims at least 30 days apart but within 12 months. Patients had to be enrolled in Medicare Parts A and B but not Medicare Advantage for the entire observation period to ensure complete claims data. Patients required an index date, defined as the date of the first qualifying MDS claim, of January 1, 2006, through December 1, 2008 ($n = 57,802$) and had to be continuously enrolled in Medicare Part D from January 2006 or their index date, whichever was later, until death or the end of the observation period (December 2008; $n = 26,107$). We excluded patients who initiated ESAs before their MDS index date, as well as patients with renal disease, because they have distinct ESA use and reimbursement patterns. Appen-

dix [Figure A1](#) (online only) provides a flow diagram of the sample selection criteria.

Analysis and Key Measures

To examine the role of cost sharing in receipt of ESAs, we analyzed the question at two levels. In the first, we described patterns of OOP payments in Part D ESA claims and compared OOP payments associated with Part D versus Part B coverage, assuming the mean units for a Part D erythropoietin alfa claim. To simulate the Part B OOP requirement, we calculated the total allowed payment under Medicare Part B (average sales price plus 6% for non-end-stage renal disease use of ESAs between January 1 and March 31, 2007).¹³ Part B reimburses 80% of the allowed rate, with the remainder designated as patient liability.¹⁴ We assumed the full 20% as the OOP payment, but note that this would represent an upper bound, because many Medicare beneficiaries have supplemental insurance. We used claims filled by beneficiaries without LIS during the initial coverage phase to calculate the Part D OOP payment for an identical claim.

We also used a two-part multivariable analysis to examine the effect of variation in Part D plan-level cost-sharing requirement and LIS receipt on ESA use. The dependent variable for the first part was any outpatient ESA during the observation period, captured based on the presence of Healthcare Common Procedure Diagnosis Coding System codes or National Drug Codes on Medicare Part B or Part D claims. For the second part, the dependent variable captured whether beneficiaries receiving ESAs had any Part D ESA claim.

Part D plan cost sharing was assigned based on the plan in which the patient was enrolled during the MDS index month. We did not have Part D plan-specific formulary data on ESA tier placement. After review of published formularies for selected large Part D plans, we made the assumption that ESAs would be placed in the highest brand tier in most plans and extracted plan-specific cost sharing for that tier as a proxy for ESA-related cost sharing. The multivariable models included indicators for whether copayment and/or coinsurance mechanisms were used by the plan for the top brand drug tier and then the reported levels (dollars or percentage) for each. To capture Part D LIS participation, we used monthly administrative enrollment indicators. Patients were assigned to either LIS or non-LIS groups if 90% of observed months were in the respective category. A small number of part-year LIS participants were excluded. Demographic characteristics included age, race, sex, income and education, region of the country, and urban-rural continuum. Health status measures, based on claims from the 12 months before the MDS diagnosis, included the Charlson comorbidity index (CCI) and a predicted value for poor performance status, denoted as disability status (DS).¹⁵ To identify individuals with LIS who received ESAs while in a long-term care (LTC) residential setting, we used specific administrative codes available on the claims.

Because the observation period varied across individuals, we used Cox proportional hazards models to estimate the risk (ie, probability) of ESA use and then, among users, whether they

Table 1. Selected Characteristics of Medicare Beneficiaries With MDS Overall and by Receipt of ESAs

Characteristic	Overall (%)	Any ESA Use (%)	Part B ESA Use Only (%)	Any Part D ESA Use (%)	P*
No. of patients	20,848	13,117	11,681	1,436	
ESA receipt					
Any	62.9				
Part B only	56.0				
Any Part D	6.9				
Part D plan cost sharing in highest brand tier†					
Copayments (% with plans that use)	72.8	73.6	74.0	70.5	< .01
Copayment (\$)/plan uses copayment					< .01
Mean	57.53	57.31	57.75	53.56	
SE	0.13	0.16	0.16	0.61	
Coinsurance (% with plans that use)	97.0	96.8	96.7	97.6	.02
Coinsurance (\$)/plan has coinsurance					< .01
Mean	28.32	29.39	29.42	29.13	
SE	0.06	0.07	0.08	0.23	
Part D LIS	36.5	35.2	30.5	73.6	< .01
Age at diagnosis, years					< .01
< 65	5.4	4.5	4.3	5.8	
65-69	7.7	7.4	7.6	5.8	
70-74	15.7	15.5	16.1	10.7	
75-79	21.3	21.8	22.3	17.7	
80-84	23.4	24.3	24.5	22.8	
85-89	17.1	17.6	17.1	21.7	
≥ 90	9.4	8.9	8.0	15.6	
Sex					< .01
Male	41.2	40.4	41.3	33.2	
Female	58.8	59.6	58.7	66.8	
Race/ethnicity					< .01
White	87.4	86.8	88.1	76.6	
Black	6.7	7.0	6.5	11.7	
Hispanic	2.2	2.4	2.2	4.2	
Other	3.6	3.7	3.3	7.5	
Median household income, quartile‡					< .01
Low	24.8	24.4	23.9	28.6	
Second	25.0	24.9	24.9	25.0	
Third	25.1	25.1	25.5	22.1	
High	25.1	25.6	25.7	24.3	
Proportion with less than high school education					< .01
Mean	0.172	0.171	0.168	0.195	
SE	0.001	0.001	0.001	0.003	
Charlson comorbidity index					< .01
0	42.8	38.9	40.2	27.6	
1	29.2	29.1	28.9	30.8	
2	13.8	15.3	14.9	18.3	
≥ 3	14.2	16.7	15.9	23.2	
Predicted poor disability status	19.5	17.4	13.5	49.2	< .01
Census region					< .01
Northeast	19.5	19.2	17.5	33.3	
Midwest	25.4	23.0	23.5	18.8	
South	40.5	43.4	44.8	32.2	
West	14.6	14.3	14.2	15.7	

NOTE. Data from 100% Medicare enrollment and claims (2005-2008), Part D plan characteristics (2006-2008).

Abbreviations: ESA, erythropoiesis-stimulating agent; LIS, low-income subsidy; MDS, myelodysplastic syndromes.

* For each row, test of significance is between beneficiaries receiving Part D ESAs and beneficiaries receiving only Part B–covered ESAs.

† Reflects cost sharing for Part D plan in which beneficiary was enrolled at MDS diagnosis, regardless of whether he or she received ESAs through Part D.

‡ Income quartile cut points are: low (< \$32,332), second (\$32,332 to \$39,917), third (\$39,917 to \$51,741), and high (≥ \$51,741).

received any ESA covered through Part D. The analyses were estimated first for the full cohort with an LIS indicator. Models were re-estimated stratifying by LIS receipt, with the expectation that LIS recipients would not be responsive to reported variations in plan-level Part D cost sharing, from which they were generally exempted. All analyses were conducted using SAS (version 9.2) and STATA software (version 12). The study was approved by the University of Maryland Institutional Review Board.

Results

The cohort included 20,848 Medicare beneficiaries with MDS, of whom 62.9% received ESAs during the observation period, but only 1,436 (6.9% overall, or 10.9% of those receiving ESAs) had any claim through Part D (Table 1); 633 received ESAs through both Parts B and D. The overall cohort was 58.8% female and 87.4% white. More than one quarter (28.0%) had a CCI ≥ 2 ; 19.5% met criteria for poor DS. More than one third (36.5%) received LIS, and 26% of those had

evidence of an LTC stay. Coinsurance was reported for the highest brand tier by almost all plans (enrolling 97.0% of beneficiaries), with a mean coinsurance rate of 28.3%. Copayment amounts were also reported for plans enrolling 72.8% of beneficiaries, with a mean copayment of \$57.53 (SE, 0.13). The cohort receiving Part D–covered ESAs was disproportionately female, nonwhite, and receiving LIS and had poor DS.

Table 2 summarizes Part D claims for ESAs, stratified by LIS status. Among initial claims, mean OOP payment for LIS recipients was \$7.65 (SE, 2.34), and $>$ half paid \$0. In contrast, patients without LIS paid a mean of \$447.36 (se, 31.58) for their first claim. Median OOP cost varied by coverage phase, ranging from \$139 in the initial phase to \$600 in the coverage gap. Prior authorization was a common feature, reported for 81.8% of initial Part D ESA claims for both LIS and non-LIS. Looking at all ESA claims, there was a moderation of payments per claim and an increase in the proportion with \$0 of cost sharing compared with initial Part D claims. Claims while an LTC resident accounted for 41.9% of LIS claims. The calcu-

Table 2. Characteristics of ESA Part D Claims by LIS Receipt

Characteristic	Initial Claims			All Part D Claims		
	LIS (n = 1,057)	Non-LIS (n = 379)	P	LIS (n = 11,554)	Non-LIS (n = 2,463)	P
Part D claims, %	73.6	26.4		82.4	17.6	
Claims per person	—	—				< .01
Mean				10.93	6.50	
SE				0.43	0.42	
Patient payment			< .01			
Mean, \$	7.65	447.36		2.47	311.01	
SE, \$	2.34	31.58		0.34	10.17	
Range, \$	0.00 to 1,946.30	0.00 to 3,909.70		0.00 to 2,022.22	0.00 to 3,987.24	
Patients with \$0 payment, %*	51.8	—	< .01	80.6	2.2	< .01
Occurring during LTC stay, %				41.9		
Coverage phase, %†			< .01			< .01
Deductible or initial coverage phase	39.2	49.1		13.4	21.9	
Coverage gap	42.1	36.7		25.2	32.8	
Catastrophic phase	18.7	12.9		61.4	43.1	
Median Part D patient payment by coverage phase, \$			< .01			< .01
Overall	0.00	187.24		0.00	106.51	
Deductible or initial coverage phase	0.00	139.07		0.00	87.26	
Coverage gap	3.00	600.05		0.00	302.28	
Catastrophic phase	0.00	102.32		0.00	60.89	
Prior authorization, %	82.3	81.8	.13	86.4	83.6	< .01
Units per claim						
Erythropoietin alfa, units			.55			.29
Mean	96,375	93,363		96,271	86,379	
SE	2,675.2	3,989.4		9,177.0	1,654.3	
Darbepoetin, mcg			.23			< .01
Mean	345	398		301	417	
SE	20.1	47.4		6.5	17.2	

Abbreviations: ESA, erythropoiesis-stimulating agent; LIS, low-income subsidy.

* Non-LIS cell in the initial claims column suppressed because of small sample size (n < 11).

† Values do not add up to 100% because of missing values for benefit coverage phase on claims.

Table 3. Cox Proportional Hazards Estimates of Effect of Part D Plan Cost Sharing and Patient Characteristics on Use of Any ESA and Part D ESA, Stratified by LIS Receipt

Outcome Variable	LIS				Non-LIS			
	Any ESA (n = 7,607)		ESA Part D Use (n = 4,621)		Any ESA (n = 13,241)		ESA Part D Use (n = 8,496)	
	HR	P	HR	P	HR	P	HR	P
Cost sharing in highest brand tier								
Type of cost sharing reported by plan								
Copayment	0.93	.24	1.24	.07	1.02	.77	1.37	.30
Coinsurance	0.99	.92	1.08	.76	1.05	.48	1.45	.28
Cost-sharing level								
Copayment (\$10)	1.02	.08	0.98	.21	1.01	.29	0.94	.23
Coinsurance (10%)	0.99	.54	1.00	1.00	0.99	.35	0.86	.06
Age at diagnosis, years								
< 65	0.78	< .01	0.88	.43	0.87	.16	1.65	.40
65-69	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
70-74	1.01	.85	0.99	.96	1.09	.11	1.28	.51
75-79	1.07	.24	1.27	.09	1.16	< .01	1.91	.06
80-84	1.07	.26	1.31	.04	1.25	< .01	2.16	.02
85-89	0.99	.81	1.72	< .01	1.34	< .01	3.28	< .01
≥ 90	1.03	.70	2.03	< .01	1.20	< .01	3.99	< .01
Sex								
Male	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Female	1.15	< .01	0.81	< .01	1.08	< .01	0.95	.60
Race/ethnicity								
White	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Black	1.05	.24	1.22	.03	1.07	.32	0.67	.34
Hispanic	1.11	.12	0.84	.22	0.89	.46	1.26	.69
Other	1.06	.33	1.18	.14	1.08	.42	1.44	.35
Median household income, quartile								
Low	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Second	1.05	.25	0.98	.85	1.02	.62	1.22	.26
Third	1.00	.97	0.89	.22	1.06	.12	1.18	.38
High	1.00	.92	1.17	.15	1.07	.09	1.44	.07
Percent with < high school education	1.01	.63	1.04	.15	1.00	.83	1.13	.03
Charlson comorbidity index								
0	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
1	1.23	< .01	1.25	.01	1.15	< .01	0.98	.87
2	1.36	< .01	1.23	.03	1.48	< .01	1.34	.05
≥ 3	1.56	< .01	1.33	< .01	1.72	< .01	1.23	.17
Predicted disability status								
Good	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Poor	0.75	< .01	2.91	< .01	0.83	< .01	3.41	< .01
Census region								
Northeast	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Midwest	1.05	.31	0.86	< .01	0.86	< .01	0.48	< .01
South	1.24	< .01	1.14	< .01	1.14	< .01	0.40	< .01
West	1.17	< .01	0.91	.01	0.91	< .01	0.55	< .01
Urbanization								
Urban	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Somewhat urban	0.92	.03	0.77	< .01	0.92	< .01	1.46	.01
Rural	0.91	.30	0.93	.73	0.72	< .01	1.33	.47

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Table 3. (continued)

Outcome Variable	LIS				Non-LIS			
	Any ESA (n = 7,607)		ESA Part D Use (n = 4,621)		Any ESA (n = 13,241)		ESA Part D Use (n = 8,496)	
	HR	P	HR	P	HR	P	HR	P
Time period of diagnosis								
First half of 2006	Ref	Ref	Ref	Ref	Ref	Ref	Ref	Ref
Second half of 2006	1.17	< .01	0.90	.25	1.11	< .01	0.85	.31
First 7 months of 2007	1.16	< .01	0.66	< .01	1.03	.44	1.04	.82
Last 5 months of 2007	1.03	.60	0.92	.40	0.88	< .01	0.92	.66
First half of 2008	0.92	.12	0.91	.38	0.82	< .01	1.00	.99
Second half of 2008	0.88	.04	0.77	.11	0.86	< .01	1.31	.27

Abbreviations: ESA, erythropoiesis-stimulating agent; HR, hazard ratio; LIS, low-income subsidy; Ref, referent.

lated Part B OOP payment of \$161 was less than half of the Part D payment (\$348) for the mean epoetin alfa claim of 86,379 units.

Table 3 lists the estimated effects of patient and plan characteristics on the risk of any ESA claim and the risk of having a Part D claim among ESA users. In the full cohort, LIS status negatively affected the probability of any ESA use (hazard ratio [HR], 0.943; $P < .01$) but, conditional on use, was associated with a large increase (HR, 4.29; $P < .01$) in Part D ESA use (data not shown). Part D cost sharing (copayments and coinsurance) had no other effects in either the LIS or non-LIS subgroups, although there was an expected trend toward decreased Part D use (HR, 0.86; $P = .06$) with increasing coinsurance rates.

In addition to cost sharing, patient age, health status, urban/rural residence, region, and time period affected receipt of ESAs and Part D ESAs. Increasing age was associated with increased ESA use in the non-LIS cohort and increased Part D claims in both groups. Increasing comorbidity (CCI) was associated with an increased risk of any ESA use in both cohorts and with higher Part D use among the LIS cohort. In contrast, poor predicted DS, which focuses on mobility limitations, was associated with a lower probability of any ESA use, but a higher probability of Part D claims, in both cohorts. As residence became less urban, both cohorts experienced decreased probability of any ESA use, and although the LIS experienced less Part D use, the non-LIS group was more likely to receive Part D ESAs.

Discussion

Understanding how implementation of the Medicare Part D benefit in 2006 affected access and use has become a major focus for policymakers as they seek to refine the benefit to improve quality and reduce costs. Understanding these effects in the Medicare beneficiary population with cancer is particularly challenging, because antineoplastic drugs and many supportive care medications have traditionally been covered through Part B, and it is not clear how the Part B and D benefits have been integrated. In this analysis, we examined whether Part D has substituted for Part B coverage of injected medications to facilitate home use or other use outside of the physician

office, drawing on the specific example of chronic ESA use in MDS. We found that only a small proportion of Medicare beneficiaries with MDS received ESAs covered through Part D and that the probability of Part D ESA claims increased substantially with LIS enrollment, with its limited cost sharing, but was not otherwise affected by variation in cost-sharing requirements by Part D plans. This may reflect limited price response by Medicare beneficiaries with cancer.^{16,17} Alternatively, our plan-level cost-sharing assignment for ESAs may have been subject to measurement error, which could have biased estimated responses toward the null. Hence, our estimated effects may be conservative.

Any effect of cost sharing within Part D is likely dominated by how Part D cost sharing compares with the alternative OOP cost under Part B. Our analysis suggests that Medicare beneficiaries without LIS would have to pay substantially more to obtain ESAs under Part D. This difference would be much greater during the coverage gap, in which the Part D payment during the study period would have been up to 4× as high as the \$348 measured during the initial coverage phase. In addition, 90% of Medicare beneficiaries have supplemental medical coverage that may further reduce patient liability under Part B but cannot cover Part D cost sharing.¹⁸ These differences in OOP cost favoring Part B coverage of ESAs administered in a physician office are likely to outweigh any difference in benefit to patients associated with reduced travel and time costs associated with Part D coverage of home administration. Most oncologists take OOP cost into account when considering treatment options,¹⁹ but even if they are unaware of Part D cost-sharing requirements upfront, they are likely to receive rapid feedback from patients facing sticker shock. Equally constraining is the requirement for prior authorization typically adopted for expensive medications such as ESAs, regardless of LIS participation. We found that an overwhelming proportion of Part D ESA claims required prior authorization. In contrast, prior authorization requirements under Part B are rare, although the Centers for Medicare and Medicaid Services implemented explicit coverage criteria for ESA use for chemotherapy-induced anemia, and local Medicare administrators

have implemented restrictions that apply to ESA use, including in MDS.²⁰

Before Part D implementation, beneficiaries with limited mobility, financial resources, and/or social supports were less likely to receive ESAs.⁹ We found that Part D coverage did not increase ESA treatment rates for these patients, particularly those with poor DS. A large proportion of Part D LIS claims occurred while beneficiaries resided in LTC facilities. Although there is a potential quality-of-life benefit for nursing home residents receiving ESAs, that scenario is not associated with substitution of home for office-based administration and the associated benefits to community-based beneficiaries.

Incentives to physicians may also be important in selection of venue for ESA administration. Under Part B, physicians are reimbursed for ESAs administered in the office setting based on the average sales price plus 6%, potentially generating substantial net revenues, whereas writing a prescription for ESAs through Part D yields no additional physician revenues. Our study did not examine the role of physician incentives in prescribing Part B ESAs, but Part B reimbursements have played a role in treatment selection for other oncology drugs.^{21,22}

This study focused on ESAs for Medicare beneficiaries with MDS. However, other drugs used chronically by patients with MDS, such as azacitidine and granulocyte colony-stimulating factor, also have the potential for home injection. The issue of Part D versus B coverage is also relevant in a variety of other conditions, such as rheumatoid arthritis.

We acknowledge a variety of limitations associated with the use of administrative data. Our MDS cohort was selected using International Classification of Diseases (ninth revision) Clinical Modification codes, which can be subject to error, and MDS may also be under-reported in some databases.²³ We recognize that Part D enrollment (relative to no coverage), participation in LIS, and even choice of Part D plan may correlate with unobserved characteristics possibly determining both therapy and drug coverage, potentially resulting in bias in our estimates. Finally, claims lack information on clinical parameters and hence cannot be used to determine appropriateness of therapy. ESAs may be overused in patients with solid tumors, and our own prior research suggests poor adherence to guidelines in MDS.²⁴ Despite these limitations, our study provides important new information concerning the use of Part D coverage and the impact of cost sharing on administration of ESAs outside of physician offices. Although our results reflect practice patterns during the earlier years of Part D, there have not been substantial changes in policy that would alter the relative gap in OOP cost sharing for ESAs provided through Part B compared with Part D.

Given concerns about the cost of the Medicare program, it is important that incentives to patients, physicians, and providers of supplemental insurance be aligned to promote efficient and patient-centered care. Part D has the potential to improve access for patients with chronic use of injected medications that

can be administered safely outside of physician offices.² The results of our study, a snapshot relatively early in the history of the Part D program, suggest that this potential is largely unrealized for beneficiaries with MDS. Higher OOP cost likely contributes to ongoing provision of ESAs in physician offices under Part B coverage. The mechanism through which Part D was implemented, with the overwhelming majority of Part D participants enrolled in a standalone prescription drug plan, may not provide incentives for efficient integration of prescription drug and medical care or for Part D plans to meet patient-centered needs, such as reduced travel cost and time. Careful examination of these issues is important to policy-makers' understanding of the impact of the program on its beneficiaries.

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Appendix

Figure A1. Sample selection flow diagram.