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Use and Spending on Biologic Disease-modifying Anti-rheumatic Drugs for Rheumatoid Arthritis among U.S. Medicare Beneficiaries

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Abstract

Objectives—Biologic therapies have assumed an important role in treating rheumatoid arthritis (RA). We sought to investigate use, spending, and patient cost-sharing for Medicare beneficiaries using biologic drugs for RA, comparing patients exposed to minimal cost-sharing because of a Part D low-income subsidy (LIS) to those facing substantial out-of-pocket costs (OOP).

Methods—We performed a retrospective, nationwide study using 2009 Medicare claims for a 5% random sample of beneficiaries with RA who had at least one RA drug dispensed. We analyzed biologic drug utilization and costs across the Part B (medical benefit) and Part D (pharmacy benefit) programs by LIS status using multinomial regression. We also projected OOP costs as the Affordable Care Act (ACA) mandates closure of the Part D coverage gap by 2020.

Results—Among 6932 beneficiaries, 1812 (26.1%) received a biologic drug. LIS beneficiaries were significantly more likely to obtain Part D home-administered biologics (RRR 2.98, 95% CI 2.50–3.56), while non-LIS beneficiaries were less likely to receive Part D biologics (RRR 0.58, 95% CI 0.48–0.69). OOP costs in Part D were lower, as expected, for LIS beneficiaries ($72 vs. $3,751/year for non-LIS). Non-LIS beneficiaries had lower costs for Part B facility-administered biologics (range $0–$2,584) than for Part D home-administered biologics. ACA reforms will narrow OOP differences between Part D and B for non-LIS beneficiaries.

Conclusions—In contrast to LIS beneficiaries who receive mostly Part D home-administered biologic DMARDs, non-subsidized beneficiaries have significant cost-based incentives to obtain facility-administered biologic DMARDs through Part B. The ACA will result in only slightly lower costs for Part D biologic drugs for these beneficiaries.

Rapid and unprecedented innovations in drug development over the last two decades have transformed the outlook of rheumatoid arthritis (RA), which once caused severe disability in many patients (1). However, newer disease modifying anti-rheumatic drugs (DMARDs) are

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expensive, and the direct costs of treating RA have increased substantially. Recent estimates indicate that RA affects over 2% of older persons, and currently 1 in 4 Medicare beneficiaries with RA receive biologic DMARDs (2, 3). Medicare spending for biologic DMARDs exceeded 1 billion dollars in 2009 (4).

Medicare insurance coverage for biologic drugs has also grown increasingly complex. For example, even within the same class, drugs administered under a physician's supervision are covered under medical insurance (Medicare Part B), while self-administered drugs are covered under pharmacy insurance (Medicare Part D). Within the Part D program, a controversial coverage gap, sometimes referred to as the "donut hole", and a subsidy to reduce out-of-pocket expenses for low-income patients add to this complexity (Figure 1). Although a few studies have examined trends in biologic DMARD use in the Medicare program, no studies have comprehensively examined utilization and costs across these different insurance benefits (3, 5).

To address this gap, we performed a nationwide study of biologic DMARD use among Medicare beneficiaries with RA. We sought to understand patterns of biologic DMARD use and how this relates to both program and beneficiary costs for Part B facility-administered versus Part D home-administered biologics. We also examined the impact of patient cost-sharing, particularly the low-income subsidy program, on costs and utilization. Finally, we estimated the impact of Affordable Care Act reforms to Part D on biologic DMARD coverage.

METHODS

The study was approved by the Centers for Medicare and Medicaid Services and was determined exempt from review by the Institutional Review Board of the University of California, San Francisco.

Data Sources

We used 2009 administrative claims for a 5% random sample of Medicare beneficiaries, including all Medicare Part B (medical insurance) and Part D (pharmacy insurance) claims. We linked these files to Beneficiary Summary Files to determine patient sociodemographic characteristics. Use of biologic drugs and expenditures were derived from Part B claims and Part D prescription drug events.

Additionally, we used information from the 2000 US Census and the Agency for Healthcare Research and Quality's ZIP-code based socioeconomic status index score as a proxy for patients' socioeconomic status (6).

Study Population

We included 6932 Medicare beneficiaries ≥65 years residing in the 50 U.S. states, who survived through the measurement year, had at least 2 face-to-face encounters with different dates of service in an ambulatory or non-acute patient setting with a diagnosis of RA (International Classification of Diseases, Ninth Revision (ICD-9) codes 714.0, 714.1, 714.2, 714.4, 714.81 or 714.89). Beneficiaries had to be continuously enrolled in Part B and a

stand-alone Part D plan so we could capture their complete utilization. They also had to have one or more prescriptions for a DMARD. All non-biologic DMARDs (hydroxychloroquine, methotrexate, leflunomide, minocycline, penicillamine, sulfasalazine, gold, cyclophosphamide, cyclosporine, azathioprine) and biologic DMARDs (etanercept, adalimumab, infliximab, rituximab, abatacept, anakinra) available in 2009 were included.

Outcome Variables

The outcomes of interest were biologic DMARD use and costs. We examined cost from two perspectives: costs to the Medicare program and beneficiary out-of-pocket (OOP) costs.

Use—To evaluate biologic DMARD use, we examined receipt of Part B facility-administered biologic DMARDs available in 2009 (infliximab, abatacept, rituximab) using the Healthcare Common Procedure Coding System (HCPS). Receipt of Part D self-injected biologics (etanercept, adalimumab, and anakinra) was identified through Part D prescription drug events.

Costs to Medicare—We calculated Medicare payment for Part B facility-administered biologic DMARDs using the Medicare Part B carrier claim payments, which reflect the actual payments made from the Medicare trust fund after deductible and coinsurance amounts have been paid. Medicare payments for 2009 Part D home-administered biologic DMARDs were calculated using the Part D total prescription cost amount paid to the pharmacy, which includes the ingredient cost, dispensing fee, and total amount attributed to sales tax.

Costs to patients—We assessed OOP costs using two different approaches. First, for Part D home-administered biologic DMARDs, we used Part D prescription drug events to tabulate the actual dollar amount the beneficiary paid that was not reimbursed by Medicare. Part B claims do not include actual OOP costs, so for facility-administered biologic DMARDs, we calculated a range of estimated costs (between 0 and 20% cost-sharing). Some Medicare beneficiaries have supplemental insurance coverage for Part B, so this group of patients may pay less than 20% (7).

Additional Variables

Our primary predictor was low-income subsidy (LIS) status. We compared the use and payments of Part B facility-administered and Part D home-administered biologic DMARDs in two groups of individuals: those who received any LIS through Part D, and those who did not. In order to qualify for a LIS, beneficiaries must meet both income and asset tests, unless they are enrolled in Medicaid, in which case they automatically receive a subsidy. The subsidy provides assistance with the premium, deductible and co-payments for prescription drugs. Individuals with a LIS are therefore exposed to minimal cost-sharing for Part D home-administered drugs while those not eligible for LIS (non-LIS) are exposed to variable cost-sharing, including 100% cost-sharing in the coverage gap (Figure 1).

Beneficiary-level sociodemographic characteristics included age, sex, and race/ethnicity. To assess medical comorbidities, we used the Charlson-Deyo comorbidity index (8). We also

included ZIP-code based socioeconomic status using an index score developed by the Agency for Healthcare Research and Quality (6). As measures of health care utilization, we examined the number of annual hospital admissions and physician office visits.

Analysis

Use—First, we described the characteristics of Medicare beneficiaries with RA using biologic DMARDs by LIS status. We then conducted a multinomial logistic regression evaluating the association of LIS status and other covariates on Part B, Part D or no biologic DMARD use. Because this model assumes the independence of irrelevant alternatives, we performed additional analyses to ensure that we were not violating this assumption.

Costs to Medicare—We calculated per-capita (i.e., among the entire population of RA beneficiaries using any DMARD) and per-beneficiary (i.e., only among biologic DMARD users) utilization and Medicare payments for biologic DMARDs by LIS status and by source of Medicare coverage (Part B vs. Part D). Mean costs were also calculated for the average number of total 30-day supplies received by beneficiaries and for a single 30-day supply. To test whether there were statistically significant differences in utilization and costs by LIS status, we used Chi-squared and Student's t-tests.

Costs to Patients—To calculate OOP costs for biologic DMARDs, we performed separate analyses for the Part D and Part B programs. For home-administered biologic DMARDs received through Part D, we calculated average beneficiary OOP costs during the deductible, initial coverage, gap ("donut hole"), and catastrophic phases (Figure 1). For facility-administered biologic DMARDs received through Part B, we calculated the potential range of OOP costs, assuming beneficiaries are liable for 0–20% of drug costs, depending on their supplemental coverage.

Finally, we projected OOP costs as the Affordable Care Act's reforms to Part D are enacted. By 2020, the legislation will eliminate the coverage gap, and require non-LIS beneficiaries to pay 25% of drug costs until reaching catastrophic coverage. Our models assume a 5% annual increase in costs starting in 2015, the latest year for which Part D benefit parameters are available. We calculated changes in beneficiary contributions assuming use of a brand-name biologic DMARD costing $1,795 for a 30-day supply, reflecting the mean cost in our 2009 analyses. We also included the Medicare Coverage Gap Discount Program, in which manufacturers provide a 50% discount on drug cost during the coverage gap (and which is counted towards the beneficiary's OOP) (9).

All analyses were performed using SAS statistical software (version 9.2; Cary, North Carolina).

RESULTS

Use

Among 6932 beneficiaries with RA, 1812 (26.1%) received at least 1 prescription for a biologic DMARD (Table 1). Thirty-two percent of beneficiaries with RA using biologic DMARDS received a LIS (vs. 29% of beneficiaries using any type of DMARD).

Table 2 shows multinomial regression results comparing biologic DMARD users to non-biologic DMARD users, with the outcome of biologic DMARD defined in categories (Part B or Part D). Compared to non-biologic DMARD users, Part B facility-administered biologic DMARD users were less likely to be older, male, black, and live in areas with higher socioeconomic status; we observed similar patterns among Part D home-administered biologic DMARD users. However, we found striking differences between groups by LIS status: Part B facility-administered biologic DMARD users were substantially less likely to have a LIS (RR 0.58, 95% CI 0.48–0.69 compared to non-biologic DMARD users) whereas Part D home-administered biologic users were more likely to have a LIS (RR 2.98, 95% CI 2.50–3.56 compared to non-biologic DMARD users).

Costs to Medicare

In Table 3a, we report *per capita* (across the entire population of RA beneficiaries using any DMARD) utilization and costs for biologic DMARDs, by benefit program (Part B or Part D) and LIS status. A larger proportion of individuals received biologic DMARDs through Part B than through Part D (16% vs. 10%). However, most LIS beneficiaries received biologic DMARDs through Part D (19% vs. 9% for Part B), while most non-LIS beneficiaries received them through Part B (18% vs. 7% in Part D). Medicare spending for biologic DMARDs per capita (i.e. among all RA beneficiaries) was $1,543 per beneficiary in the Part D program, and $2,039 per beneficiary in the Part B program.

In Table 3b, we report utilization and Medicare costs at the level of the individual beneficiary. Overall, costs were lower per beneficiary for Part B facility-administered DMARDs ($12,920 vs. $14,902 in Part D). The difference in Part B vs. Part D costs were not accounted for by differences in the number of 30-day supplies filled. Even though the number of 30-day supplies dispensed was slightly higher for Part B facility-administered biologic DMARDs (9.7 vs. 8.5 for Part D), the per-30-day-supply cost remained lower for Part B biologics ($1,363 vs. $1,814 in Part D). When comparing costs for LIS and non-LIS beneficiaries, Medicare payments for biologic DMARDs in Part D were not statistically different ($15,134 vs. $14,700, p=0.42); however, in Part B, Medicare spent less on biologic DMARDs for LIS beneficiaries ($11,884 vs. $13,135; p=0.04).

Costs to Patients

OOP costs are presented in Tables 4a and 4b. In Part D, we present costs across the different benefit phases, including the coverage gap (Table 4a). As expected, LIS beneficiaries have low costs, averaging $72/year. Among non-LIS beneficiaries, annual OOP costs averaged $3,751, with the majority of cost incurred during the coverage gap period (average $2,140).

Because we lacked information on supplemental insurance coverage, we calculated a range of possible OOP costs in Part B (Table 4b). Costs could range from $0 for those with the most comprehensive supplemental coverage to $2,584 for those liable for the maximum 20% coinsurance for drug costs.

Finally, in Table 5 we projected costs as Affordable Care Act policies unfold over the next five years. Non-LIS Beneficiaries using Part D self-administered biologic DMARDs will

continue to see high OOP costs, but these costs will gradually decrease to be more commensurate with facility-administered biologic DMARD costs in Part B. For a 12-month supply of a Part D biologic DMARD, we project that beneficiary true out-of-pocket contributions will be $2,588 after accounting for the Medicare Coverage Gap Discount Program in 2020. Beneficiaries will exit the coverage gap more quickly because of the discount program and will accumulate OOP costs largely in the catastrophic phase of coverage. During catastrophic coverage, beneficiaries are liable for 5% of drug costs, so OOP expenses will continue to be sensitive to biologic DMARD retail pricing.

DISCUSSION

In this study, we performed a comprehensive evaluation of use and costs for newer RA drugs in the Medicare program. Our findings shed light on the complexity of current Medicare drug coverage policies for biologic DMARDs. In 2009, Medicare spent a substantial amount on biologic DMARDs in 2 separate programs. Somewhat surprisingly, we found a majority of spending occurred in the Part B program, which covers infusible biologic DMARDs administered under physician supervision. A minority of patients received biologic DMARDs through the Part D pharmacy benefit (40%). In our adjusted analyses, the presence of a Part D low-income subsidy (LIS) was the most important predictor of the program under which biologic DMARDs were obtained.

As we examined OOP costs to patients under each program, potential cost-based incentives for receiving biologics covered through Part B vs. Part D became apparent. Individuals with the LIS had very low OOP costs for Part D biologics (totaling $72/year). Conversely, beneficiaries without a LIS subsidy paid more OOP for biologic DMARDs received through Part D (totaling $3,751 per year) compared with a maximum of $2,584 through Part B. Thus, whereas LIS individuals do not necessarily have a financial incentive for choosing which type of biologic DMARD to receive, non-LIS individuals have a significant financial incentive to choose facility-administered Part B biologic DMARDs.

The peculiarities of the Medicare benefit system and data in our study showing that patients choose to receive self-injectable biologic DMARDs through Part D when OOP costs are essentially eliminated suggest that in the absence of financial incentives, more patients would choose home-administered biologic DMARDs. Because it is unlikely that Medicare beneficiaries with low socioeconomic status have systematically different preferences for the mode of drug administration, the LIS group can effectively serve as a control group for evaluating current policy. The reasons for preferring home-administered biologic DMARDs in the absence of financial incentives are likely multi-factorial, and include a greater number of biologic DMARDs available for self-injection, the convenience of administering injections at home without a physician visit, and less lost productivity from work or other activities (10). If these assumptions are accurate, then our results suggest that high cost-sharing has shifted demand to the Part B program for at least some non-subsidized individuals.

These utilization patterns raise several important policy issues. First, very high cost-sharing in Part D may limit patient choice and increase demand in the Part B program for biologic

DMARDs for the roughly two-thirds of Medicare beneficiaries who do not receive low-income subsidies. Second, administration of Part B biologic therapy requires intravenous access and treatment in a physician's office or an outpatient hospital department, posing concerns about potentially higher indirect costs given time away from other activities. Third, our results suggest that for the same class of drugs with similar efficacy, Medicare is providing greater subsidies in the Part B program for many beneficiaries, which may create a competitive advantage to companies producing physician-administered biologic DMARDs. Fourth, the complexity of the program poses a significant administrative burden for practices faced with helping patients navigate their benefits.

These issues have led many to recommend fundamental reform to specialty drug coverage in the Medicare program to address issues of access and efficiency. In a 2009 report to Congress, the Medicare Payment Advisory Committee suggested three payment reform options to explore for biological drugs and emerging biosimilars: reference pricing, payment for results, and bundling (4). Four years later, these strategies are still not widely used in the U.S. health care system. Another proposal has been to examine the potential impact of consolidating Medicare reimbursement for drug categories with overlapping Parts B and D coverage. In 2010, CMS commissioned a report that found that on average, patients requiring RA drugs would face higher cost sharing if coverage was consolidated under Part D (11). This conclusion is supported by our data.

Unfortunately, the Affordable Care Act (ACA) is unlikely to eliminate the financial burden for high cost specialty drugs for patients with RA who do not meet eligibility requirements for a low-income subsidy. A key reform of the ACA is to cap cost-sharing during the Part D coverage gap from 100% to 25% coinsurance by 2020. For individuals taking low cost generic medications, this will decrease cost-sharing and out-of-pocket costs overall. However, for high-cost specialty drugs, where spending in the initial coverage period is high because of high coinsurance, a drop to 25% during the gap represents a relatively modest reduction in financial burden. Many biologic drug users will continue to reach the catastrophic phase of coverage before experiencing a decrease in costs. Therefore, non-subsidized Part D beneficiaries requiring biologic DMARDs will continue to have high OOP costs, although our analyses demonstrate that costs in Part D will become slightly lower over time. This suggests that cost-based incentives for obtaining biologic DMARDs through the medical benefit may somewhat decrease over time.

Other policies in the ACA may promote greater use in the Part D program. For example, the ACA has created Accountable Care Organizations (ACOs) as part of the "shared savings initiative," aiming to incentivize care coordination to improve quality and reduce costs. Because savings calculations used to evaluate ACOs are based on Parts A and B (but not Part D) expenditures, prescription shifts to Part D could increase the appearance of cost-savings. This may have the unintended consequence of increasing the financial burden faced by middle-income patients who face higher drug costs in Part D, and could reduce drug access and adherence. How these future incentives will play out in the health care marketplace remains to be seen.

Our study has some important limitations. First, we were only able to estimate a range of potential OOP costs in the Part B program because we did not have access to data on supplemental coverage or more detailed billing information from individual practices. Second, we did not have information on individual patient preferences, disease severity, or other clinical or patient factors influencing choice of biologic drug. Third, because our focus was on use and patient and program costs, we did not investigate the influence of individual physician practice patterns; at least one previous study suggests that practice variation also plays a role in biologic drug choice (3).

As health reform continues, a coordinated approach to drug coverage will be needed to manage costs and ensure equitable access to treatments. This will be especially urgent in conditions such as RA, where the number of expensive specialty drugs is expected to grow. Our data suggest that patient cost-sharing is an important determinant of drug choice in Medicare's Part B versus Part D programs, and that the current system risks significant financial burden to many patients. Future policy reforms to Medicare's drug benefit program should address the limitations of the current highly complex coverage system while testing new payment models for high cost specialty drugs.

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Significance

- Our findings shed light on the complexity of current Medicare drug coverage policies for biologic DMARDs.
- A majority of spending for biologic DMARDs occurred in the Part B program, which covers facility-administered drugs, rather than the Part D program, which covers home-administered drugs dispensed by a pharmacy. Low-income subsidy beneficiaries, who have low out-of-pocket pharmacy costs, were significantly more likely to receive Part D biologics than those without a subsidy.
- Non-subsidized beneficiaries face high out-of-pocket costs for Part D biologic DMARDs, and Part D reforms recommended in the Affordable Care Act will only slightly lessen this burden.

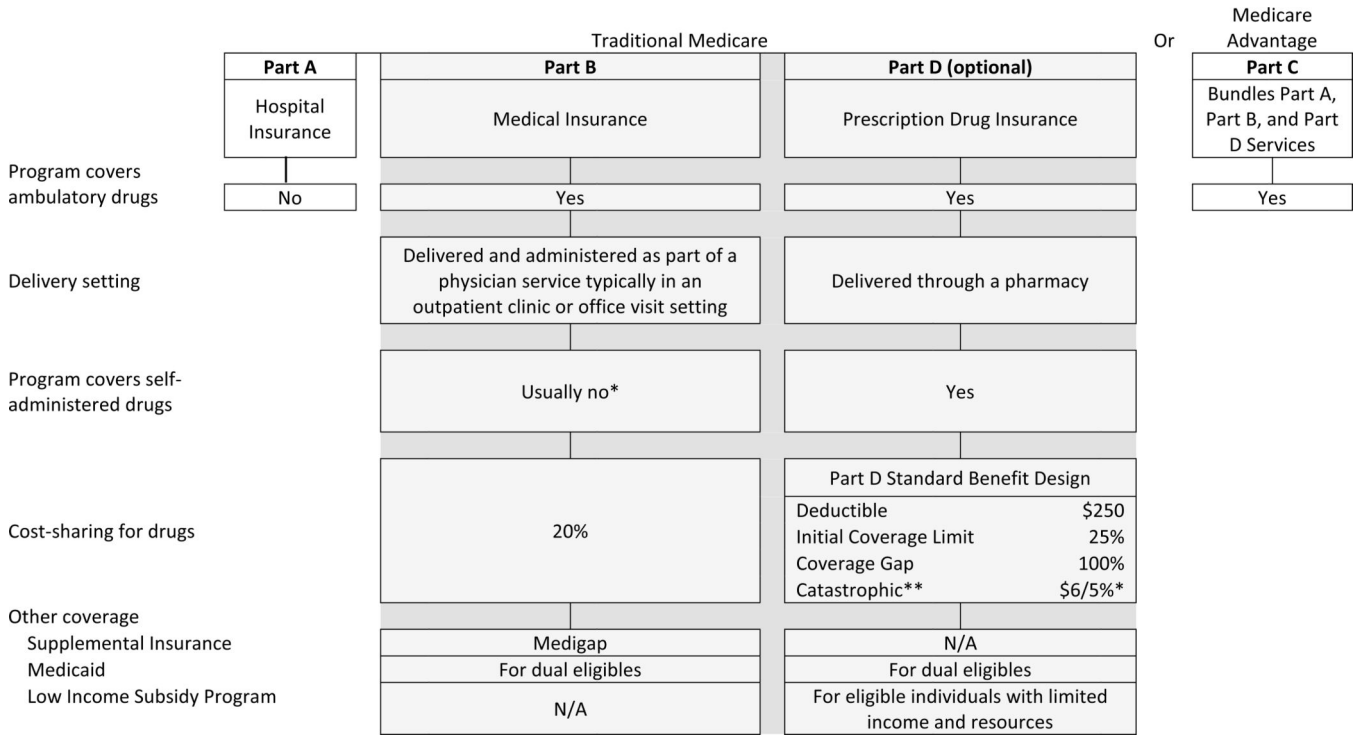

Figure 1.

Benefit Structure for Ambulatory Biologic Drug Coverage in the Medicare Program in 2009. The present study examines biologic drug use for rheumatoid arthritis under Part B and Part D insurance, shaded in gray.

*Under certain circumstances, Part B may provide coverage for some self-administered immunosuppressive therapies, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, certain oral cancer drugs, and certain drugs necessary to use Durable Medical Equipment.

**Catastrophic Coverage is the greater of $6 or 5% once beneficiaries reach a certain spending threshold ($4,350 in 2009).

Table 1

Selected characteristics of Medicare beneficiaries with rheumatoid arthritis in 2009.

Characteristics	Beneficiaries with RA using any DMARDs* (N = 6932)	Beneficiaries with RA Using Biologic DMARDS (N = 1812)
Mean age (SD)	75.7 (6.5)	74.7 (6.0)
Female, n (%)	5651 (82)	1515 (84)
Race/ethnicity, n (%)		
White	5959 (86)	1580 (87)
Black	563 (8)	114 (6)
Other	410 (6)	118 (7)
Mean Charlson comorbidity score (SD)	1.5 (0.9)	1.5 (0.9)
Area-level socioeconomic status index		
Quintile 1 (counties with lowest % SES)	45.3 (2.0)	45.3 (1.9)
Quintile 2	48.4 (0.6)	48.4 (0.6)
Quintile 3	50.2 (0.5)	50.2 (0.7)
Quintile 4	52.3 (0.7)	52.3 (0.7)
Quintile 5 (counties with highest % SES)	56.1 (2.5)	56.0 (2.3)
Low-Income Subsidy, n (%)	2015 (29)	572 (32)
Number of physician visits, mean (SD)	13.4 (9.5)	15.4 (10.2)
Number of hospitalizations, mean (SD)	0.3 (0.8)	0.4 (0.8)
Use of non-biologic DMARDs, n (%)	6443 (93)	1323 (73)
Use of biologic DMARDs, n (%)	1812 (26)	
Part B biologic DMARD	1094 (16)	1094 (60)
Part D biologic DMARD	718 (10)	718 (40)

RA=rheumatoid arthritis; DMARD=disease-modifying anti-rheumatic drug; SES=socioeconomic status.

*Including any non-biologic or biologic DMARD.

Table 2

Multinomial logistic regression model examining factors associated with biologic DMARD use in Medicare beneficiaries with rheumatoid arthritis using DMARDs.

	RRR (95% CI)	
	Biologic DMARD use (vs. non-biologic DMARD use)	
	Part B Biologic DMARD	**Part D Biologic DMARD**
Age		
65–72	1	1
73–78	0.99 (0.85, 1.16)	**0.73 (0.60, 0.88)**
79+	**0.73 (0.62, 0.86)**	**0.49 (0.40, 0.60)**
Gender		
Male	**0.77 (0.64, 0.92)**	0.85 (0.69, 1.06)
Female	1	1
Race/ethnicity		
Black	**0.56 (0.41, 0.77)**	**0.66 (0.49, 0.88)**
Other	0.81 (0.58, 1.14)	1.07 (0.81, 1.43)
White	1	1
Charlson comorbidity score		
1	0.90 (0.72, 1.12)	**0.78 (0.61, 0.99)**
2	0.80 (0.62, 1.03)	0.80 (0.61, 1.06)
3+	1	1
Subsidy Status		
Non-LIS	1	1
LIS	**0.58 (0.48, 0.69)**	**2.98 (2.50, 3.56)**
Area-level SES		
Quintile 1 (lowest SES)	0.91 (0.73, 1.13)	**0.77 (0.61, 0.98)**
Quintile 2	0.85 (0.69, 1.05)	**0.56 (0.43, 0.73)**
Quintile 3	**0.80 (0.65, 0.98)**	**0.57 (0.44, 0.74)**
Quintile 4	0.96 (0.79, 1.18)	**0.61 (0.47, 0.79)**
Quintile 5 (highest SES)	1	1
Number of hospitalizations		
0	0.78 (0.60, 1.02)	**0.74 (0.55, 0.99)**
1	0.94 (0.70, 1.26)	0.80 (0.56, 1.12)
2+	1	1

DMARD=disease-modifying anti-rheumatic drug. LIS=low-income subsidy. SES=socioeconomic status. RRR=relative risk ratio.
The outcome in this multinomial logisitic regression model is biologic DMARD use, categorized by whether the biologic DMARD was obtained in Part B versus Part D. The RRRs therefore represent a comparison between biologic DMARD users in each program to non-biologic DMARD users with rheumatoid arthritis.

Table 3

a. *Per capita utilization and Medicare payments for biologic therapy among beneficiaries with rheumatoid arthritis, by low-income subsidy status and source of insurance coverage.**

Among all beneficiaries with RA receiving any DMARDs**	Total (N = 6932)	Non-LIS (n = 4917)	LIS (n = 2015)	P value
Any biologic DMARD, % receiving	26	25	28	0.006
Part D biologic	10	7	19	<.0001
Part B biologic	16	18	9	<.0001
Medicare payment, Total $, per capita				
Any biologic DMARD	3,582	3,448	3,910	0.01
Part D biologic	1,543	1,028	2,801	<.0001
Part B biologic	2,039	2,420	1,109	<.0001

b. *Per beneficiary* utilization and Medicare payments for biologic therapy among beneficiaries with rheumatoid arthritis, by low-income subsidy status and source of insurance coverage.

Among beneficiaries with RA receiving biologic DMARDs	Total (N = 1812)	Non-LIS (n = 1240)	LIS (n = 572)	P value
Any biologic DMARD, % receiving				
Part D biologic DMARD	40	27	67	<.0001
Part B biologic DMARD	60	73	33	<.0001
Medicare payment, Total $, per user				
Part D biologic DMARD	14,902	15,134	14,700	0.42
Part B biologic DMARD	12,920	13,135	11,884	0.04
Number of 30-day supplies among users				
Part D biologic DMARD	8.5	8.7	8.2	0.06
Part B biologic DMARD	9.7	9.8	8.9	0.001
Medicare payment, Total $, per user for a 30-day supply				
Part D biologic DMARD	1,814	1,795	1,839	0.24
Part B biologic DMARD	1,363	1,367	1,345	0.69

* Per capita refers to the cost distributed across the entire population of individuals with RA using any DMARD.

** Including any non-biologic or biologic DMARD.

RA=rheumatoid arthritis. LIS=low-income subsidy. DMARD=disease-modifying anti-rheumatic drug.

Table 4

a. Part D out-of-pocket (OOP) costs for biologic DMARDs, by subsidy status and Medicare Standard Benefit design in 2009.

			Deductible and Initial coverage period			Coverage gap period			Catastrophic coverage period		
			$295 deductible; 25% coinsurance – up to $2,700 of total drug costs			100% of drug cost from $2,700 – $6,514			The greater of 5%, or $6		
Annual OOP Costs, Mean			Mean # RX, OOP Costs, % of Total OOP Cost								
	N	OOP	# Rx	OOP	% of Total OOP	# Rx	OOP	% of Total OOP	# Rx	OOP	% of Total OOP
Biologics	626	$1,647	0.8	$179	11%	1.7	$944	57%	6.0	$523	32%
Non-Lis	268	$3,751	0.8	$397	11%	1.8	$2,148	57%	5.8	$1,205	32%
Lis	358	$72	0.8	$15	21%	2	$44	61%	6	$13	18%

b. Part B out-of-pocket (OOP) costs for biologic DMARDs, by minimum and maximum supplemental insurance coverage amounts in 2009.

Annual Medicare payment, Mean			Range of OOP
	N	Medicare payment	Assuming 0% –20% supplemental insurance coverage
Biologics	1,094	$12,920	$0 – $2,584

Table 5

Projected impact of Part D reforms under the Affordable Care Act on out-of-pocket (OOP) spending for brand-name biologic DMARDs, assuming average 2009 drug costs.

Benefit Period	Description	2009	2013	2014	2015	2016	2017	2018	2019	2020
Deductible Period	Deductible threshold. A beneficiary pays 100% of drug costs until the deductible threshold.	$295	$325	$310	$320	$336	$353	$370	$389	$408
Iniitial Coverage Period	Initial Coverage (ICL) Threshold. A beneficiary pays 25% of drug costs after the Deductible and until the ICL Threshold is reached.	$2,700	$2,970	$2,850	$2,960	$3,108	$3,263	$3,427	$3,598	$3,778
Coverage Gap Period	OOP Threshold. A beneficiary pays coinsurance (varies by year, per below) until OOP Threshold is reached.	$4,390	$4,750	$4,550	$4,700	$4,935	$5,182	$5,411	$5,713	$5,999
	Beneficiary pays coinsurance (applied toward OOP Threshold) Manufacturer discount (applied toward OOP Threshold) Part D Plan pays	100% N/A 0%	47.5% 50% 2.5%	47.5% 50% 2.5%	45% 50% 5%	45% 50% 5%	40% 50% 10%	35% 50% 15%	30% 50% 20%	25% 50% 25%
Catastrophic Coverage	Once total OOP threshold is reached, beneficiaries enter Catastrophic Coverage Period and pay 5% of drug costs.	5%	5%	5%	5%	5%	5%	5%	5%	5%
Calculated total beneficiary payment during the year*		$3,444	$2,671	$2,602	$2,605	$2,686	$2,671	$2,640	$2,622	$2,588

Values shaded in gray reflect a 5% annual increase in thresholds starting in 2015, the latest year CMS Medicare released Part D standard benefit paramters and cost thresholds are available. Starting in 2011, the Medicare Coverage Gap Discount Program makes available manufacturer discounts for applicable, covered Part D drugs. Thes discounts count towards patient OOP spending, and therefore result in beneficiaries reaching the catastrophic phase of coverage more quickly.

* Total beneficiary payments (or true OOPs) were calculated assuming 12 fills of brand name biologic DMARDs costing $1,795 for a 30-day supply (the mean cost in our analysis, see Table 3b.)