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Coverage For High Cost Specialty Drugs for Rheumatoid Arthritis in Medicare Part D

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Abstract

Objective—One in four Medicare beneficiaries with rheumatoid arthritis (RA) use high cost biologic disease modifying drugs (DMARDs), and spending for these drugs has risen sharply for Medicare Part D. We conducted the first systematic, national investigation of how Part D plans cover biologic DMARDs and patients' financial burden under current cost-sharing structures.

Methods—We performed a cross-sectional analysis of Part D plans' formularies (n=2,737) in 50 states and Washington, DC using the January 2013 Centers for Medicare and Medicaid Services Prescription Drug Plan Formulary and Pharmacy Network Files. We calculated the percentage of plans covering each DMARD, prior authorization (PA) requirements, and copayments charged. We also compared biologic drug coverage in Medicare Advantage plans to stand-alone Part D plans.

Results—All plans covered at least 1 biologic DMARD, but the vast majority required PAs (97%). Nearly all plans (81% to 100%) required a percentage coinsurance (average 29.6% of drug cost) rather than a fixed dollar copayment. This translated into mean out-of-pocket costs of

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$2,712–$2,774 before reaching the catastrophic phase of coverage, during which beneficiaries pay 5% of drug costs. Medicare Advantage plans covered more individual biologic DMARDs (55% to 100%) than stand-alone drug plans (22% to 100%), but charged higher average coinsurance (31.1% vs. 29.0%). In contrast, 6 of 9 non-biologic DMARDs were covered by nearly all plans without PAs at fixed copayments averaging $5–$10 per month.

Conclusion—Nationally, nearly all Part D plans cover at least one biologic DMARD, but the vast majority require sufficiently high cost sharing to risk significant financial burden to patients.

Management of many chronic conditions has improved dramatically in the last decade with the advent of novel specialty drugs, which are often both life-changing and costly. This is particularly true for rheumatoid arthritis (RA), a condition affecting 1.3 million people in the United States (1). Prior to the late 1990s, RA was among the most debilitating chronic conditions, with one in three patients permanently disabled within five years (2, 3). In 2014, disease control is possible for many patients with early and aggressive treatment using disease modifying anti-rheumatic drugs (DMARDs), now standard components of guideline-based care (4, 5). However, newer biologic DMARDs can cost over $20,000 annually, and even with insurance, many patients who require them after failing first-line drugs for disease control will face a significant financial burden for treatment (6–9). A national survey of 1,100 adults with RA found that 1 in 6 decreased medication use due to cost, potentially resulting in worse outcomes (10).

Because biologic DMARDs are both efficacious and expensive, understanding how to cover and pay for them is an important policy issue. Since RA affects 2.3% of older persons and over 1 in 4 Medicare beneficiaries with RA receive biologic DMARDs, Medicare spending in this area is large, exceeding a billion dollars in 2009 (11, 12). Insurance coverage for biologic DMARDs by Medicare has grown increasingly complex. Biologic DMARDs were historically covered only under Medicare's medical insurance (Part B) as physician-administered drugs. With the introduction of the Part D pharmacy benefit in 2006, coverage was significantly expanded to include self-administered biologic DMARDs dispensed through a pharmacy. Despite the projected growth in Medicare spending on biologic DMARDs in Part D, no studies have systematically examined how Part D plans nationwide cover biologic DMARDs or the financial implications of current coverage policies.

To address this gap, we conducted a nationwide examination of 2013 Part D plans' coverage of biologic and non-biological DMARDs. We investigate the level of cost sharing for patients and also analyze how Medicare Advantage versus stand-alone drug plans structure cost sharing by using prior authorizations (PA), specialty tiers, and coinsurance versus fixed dollar copayments. Our findings shed light on how Part D currently provides coverage for biologic DMARDs and the potential impact of Part D changes included in the Affordable Care Act.

METHODS

Data Source

All Medicare Part D stand-alone (PDP) plans and Medicare Advantage prescription drug plans in 50 states and Washington D.C. (n=2,737) were examined using the January 2013

Centers for Medicare and Medicaid Services Prescription Drug Plan Formulary and Pharmacy Network Files. Special needs plans (n=643) were excluded since they target subgroups of beneficiaries (e.g. institutionalized) and may have specialized formularies. Data for each plan included formulary information (coverage, PA, specialty tier) and cost-sharing structure (e.g. 25% coinsurance vs. $15 copay).

Coverage Analysis

Analyses included 9 biologic (abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, rituximab, tocilizumab) and 9 non-biologic DMARDs (azathioprine, cuprimine, cyclophosphamide, cyclosporine, hydroxychloroquine, leflunomide, methotrexate, minocycline, sulfasalazine) based on the 2012 American College of Rheumatology RA guidelines and the National Committee for Quality Assurance's DMARD quality measure (4, 13). At the time of the study (January 2013), several biologic drugs were available only by intravenous infusion and usually administered under the supervision of a physician, such as infliximab, rituximab, and tocilizimab. Abatacept was available by either infusion or subcutaneous injection. In instances where an infusible form of a medication is available, the drug is generally covered under medical insurance (Medicare Part B), and therefore not covered by Part D. However, there may be instances when Part D covers infusible drugs (e.g. home health) (14), so for completeness, we analyzed all available biologics for RA.

We examined formulary coverage for each drug, calculating the percentage of plans covering each drug, how often PAs were required, use of specialty tiers, whether patients' cost-sharing was based on coinsurance (e.g. percentage of drug costs) or a fixed dollar copayment, and mean and median monthly out-of-pocket costs for patients. We investigated whether costs or coverage policies differed for stand-alone PDP plans versus Medicare Advantage plans. National averages for each drug were obtained by first averaging across all plans in each county, then across all counties in each state, and lastly across all states and Washington D.C.

We also examined the potential out-of-pocket cost that Medicare beneficiaries might experience for a single biologic DMARD under 2014 Medicare Part D (Table 1). In 2014, beneficiaries paid a $310 deductible, followed by an initial coverage phase where drugs were covered, but beneficiaries paid a fixed dollar copayment or percentage coinsurance as required by their plan. For this phase, we estimated copayments based on average coinsurances for each drug, since percentage coinsurances were the form of cost-sharing adopted by most plans for biologic DMARDs. Once total drug costs (paid by beneficiaries and the plan) reached $2,850, beneficiaries then entered the gap phase of coverage (or "donut hole") and paid 47.5% coinsurance until the sum of their out-of-pocket costs and manufacturers' discounts reached the catastrophic threshold of $4,450. Finally, during catastrophic coverage, out-of-pocket costs decrease, with cost-sharing reduced to 5% coinsurance for brand-name drugs for the rest of the year.

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RESULTS

Biologic DMARDs

All Part D plans covered at least one biologic DMARD, however 97% of plans required PA approval. Coverage for individual biologic DMARDs ranged from 30–100% of plans (Table 2). Out-of-pocket costs were significant, with a mean of $835/month (median $842) across all drugs and with an average ranging from $269/month (infliximab) to $2,993/month (anakinra).

The great majority of plans (81–100% of plans, depending on the DMARD) required patients to pay a percentage coinsurance rather than a fixed dollar copay, with coinsurance averaging 29.6% of drug costs across all biologic DMARDs. Most plans placed biologic DMARDs in specialty tiers (95%).

Medicare Advantage prescription drug plans were more likely to cover biologic DMARDs (mean 79%; range 55% to 100% for individual drugs) compared to PDPs (mean 69%; range 22% to 100% for individual drugs), but across all biologic DMARDs, charged slightly higher average coinsurance (31.1% vs. 29.0%) and out-of-pocket costs (mean costs $862/month vs. $829/month) (Table 3).

Under a standard 2014 Part D benefit (Table 1), beneficiaries would pay between $2,712 to $2,774 for biologic DMARDs before reaching catastrophic coverage, where costs continue to accumulate, but more slowly (Table 4). Even during the covered phase, beneficiaries would pay on average 29.6% coinsurance or $269 to $2,993 out-of-pocket per month depending on the drug. Most beneficiaries therefore would experience very high out-of-pocket costs even with Part D benefits.

Non-biologic DMARDs

In comparison, most non-biologic DMARDs were covered by the majority of plans at low fixed dollar copayments and without PA restrictions (Table 2). Six of 9 non-biologic DMARDs had average out-of-pocket costs of $10/month or lower ($120 annually). For the least expensive non-biologic DMARD covered by each plan, the average copay was $4 per month or $48 in annual out-of-pocket costs.

Both Medicare Advantage prescription drug plans and PDP plans covered nearly all non-biologic DMARDs, with most charging fixed dollar copays that averaged $4 to $34 for all but one non-biologic DMARD (Table 3).

DISCUSSION

Our nationwide study of Medicare Part D drug plans found that while all plans cover at least one biologic DMARD, access is highly controlled through prior authorization requirements, and beneficiaries face significant cost-sharing, spending approximately $2,700 for a single biologic DMARD before reaching the catastrophic phase of coverage. Out-of-pocket spending then continues to accumulate but rises more slowly, with beneficiaries paying 5% coinsurance during the catastrophic phase of coverage. A 2006 study of low-income Medicare beneficiaries in the first year of Part D estimated that out-of-pocket costs for biological DMARDs would exceed $4,000 annually (8). Our findings indicate that eight years after implementation, Part D plans continue to use high cost sharing as a primary cost-control mechanism for biologic DMARDs, placing a substantial financial burden on patients who require such drugs for adequate control of their RA symptoms.

Earlier studies have examined the use of PAs, specialty tiers, and coinsurance for biologic DMARDs and other expensive specialty drugs (8, 15). We found that in 2013, Medicare Part D plans are already near saturation in adoption of PAs (95%) to ensure appropriate biologic DMARD use. However, even when use is deemed appropriate, plans have increasingly instituted high coinsurance, leaving patients with very high out-of-pocket costs. This may be counter to the rationale for expansion of drug coverage: to reduce out-of-pocket costs, increase treatment adherence, and prevent morbidity. Biologic DMARDs show greater price inelasticity compared to drugs used to treat less symptomatic diseases (16). For example, in one study of 45 health plans, models indicated that if a plan doubled cost-sharing for RA-related specialty drugs, overall spending on these drugs would fall only by 21%, as opposed to traditional pharmaceuticals, for which spending falls as much as 30–50% when copayments double (16). However, increased cost sharing is still associated with underuse of biologic DMARDs and appears to shift financial burden to other medical and non-medical areas (6, 16). In one study of Medicare beneficiaries with RA, 12% reported decreased spending on basic needs because of medication costs (10).

Unfortunately, the Affordable Care Act (ACA) is unlikely to significantly lessen the financial burden for high cost specialty drugs for patients with RA. A key reform of the ACA is to cap beneficiaries' cost sharing during the Part D coverage gap (47.5% coinsurance for brand-name drugs in 2014) to a maximum 25% coinsurance by 2020. While this improves access for traditional drugs, our findings show that beneficiaries with RA already pay on average 30% coinsurance for biologic DMARD costs prior to the coverage gap, and capping their coinsurance at 25% during the coverage gap represents a very modest reduction in financial burden. Many Part D beneficiaries requiring biologic DMARDs will have sufficient out-of-pocket costs to reach catastrophic thresholds in total drug spending each year. Clinicians caring for individuals with RA should be aware of this and be prepared to discuss long-term affordability as well as relative efficacy of biologic DMARDs with their patients to help them make informed decisions about treatment. Currently, cost discussions occur in only one-third of RA office visits where changes are made to RA drug treatment (17).

A critical question raised by our analyses is whether the three primary cost and coverage policies in Part D plans (prior authorizations, specialty tiers, high patient coinsurance), appropriately address the issue of value, that is whether the high cost of biologic DMARDs is commensurate with improved outcomes. ACR guidelines recommend that biologic DMARDs be used primarily in patients who continue to exhibit significant disease activity despite an adequate trial of non-biologic DMARDs (4). Although there is professional consensus and robust clinical trial evidence of the effectiveness of biologic DMARDs in achieving disease control in RA in patients who have failed first-line therapies, cost-effective analyses were not included in the ACR guideline, and have not been used to inform Medicare's coverage policies. Given that four of the five top drugs in terms of sales/revenue in 2013 (adalimumab, infliximab, rituximab, and etanercept) have indications for RA, that new small molecules and biological DMARDs are expected to come to market, and the anticipated high costs of future biosimilars, addressing the issue of value in a more systematic way will become more urgent (18). Theoretically, the move toward population health models and global budgets through ACA programs such as Accountable Care Organizations (ACOs) may stimulate innovation in this area in the future.

Other nations have addressed the high cost of specialty drugs using a variety of strategies, many of which are based on overall cost-effectiveness. In the United Kingdom (UK), the National Institute for Care and Excellence (NICE) performs cost-effectiveness analyses to inform coverage decisions (19). Because many biologic DMARDs have favorable cost-effectiveness profiles for patients failing non-biologic DMARDs, the UK's National Health Service covers specific biologic DMARDs with minimal cost-sharing, generally in the form of a fixed copayment. Similar programs have been instituted in other European nations and Canada (20). In these countries, national health insurance pays for both drug and medical coverage, covering drugs that scientific evidence suggests have value for patients, the health system, and society. However, drug costs in many of these countries are often significantly lower than in the United States, affecting value determinations and making it difficult to extrapolate directly to the U.S. health care system. A variety of strategies are used internationally to control drug costs. For example, most members of the Organization for Economic Cooperation and Development (OECD) use some version of either least cost alternative (LCA) policies or reference drug pricing, in which the payment rate of a drug is set to the payment rate of a less costly but comparable drug (12). Such strategies have largely failed to gain momentum in the United States because of concerns regarding dis-incentivizing pharmaceutical investments in research and development or reducing patient access to new drugs.

Also in contrast to other countries, for Medicare, the ties between drug coverage (Part D) and medical coverage (Part A and B) tend to be looser, allowing beneficiaries to purchase drug and medical coverage separately from different insurers. Thus, stand-alone Part D plans can require high cost sharing for specialty drugs like biologic DMARDs without facing the potential consequences of increased expenditures from office visits and hospitalizations. Surprisingly, our study found that more integrated Medicare Advantage prescription drug plans did not have lower cost-sharing compared to stand-alone Part D plans; coverage was slightly broader, but Medicare Advantage prescription drug plans require greater out-of-pocket costs for biologic DMARDs mostly because of higher percent

coinsurances. This may be because multiple Medicare Advantage prescription drug plans exist on the market, and more generous benefits may risk drawing sicker patients, in contrast to other nations where a single payer system may reduce patient selection pressures.

A limitation of our study is that we did not weight cost by plan enrollment, but our analyses were meant to reflect Part D options for policy purposes. However, because there was little variation in cost structures across plans, our findings and conclusions would be similar even with such weighting. We also did not look at actual out-of-pocket costs; the increasing use of mechanisms such as pharmaceutical manufacturer drug coupons may decrease out-of-pocket costs for some patients; although Medicare does not allow such coupons because of anti-kickback statutes, there is evidence that they are used nonetheless (21, 22). Moreover, many beneficiaries are on multiple medications for RA and other comorbid conditions and likely face even greater financial burden from drug costs.

The issue of covering high cost specialty drugs such as biologic DMARDs is not unique to Medicare, but also affects commercial insurers and younger individuals. The ACA now requires insurers to enroll individuals regardless of pre-existing conditions and drug coverage is mandated. Biologic DMARDs are an important example of expensive new drug therapies with potential to improve patients' lives when used appropriately, but where significant financial burdens may disincentive use and lead to potentially worse outcomes (23, 24). At the same time, failure to contain costs may undermine efforts to slow health care spending in the United States, particularly given the substantial growth expected in this area (12).

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 (12). Four years later, these strategies are still not widely used in the U.S. health care system. Moreover, our study indicates that current strategies primarily use high cost-sharing for biologic DMARDs and risk substantial financial burden to patients. With newer biologic drugs for many chronic conditions continuing to reach the market, a comprehensive approach that considers total costs to both the patient and society in terms of work disability, quality of life, and premature mortality is needed. As health reform advances, Americans may be better served if drug coverage moved away from high coinsurance to focusing on payment and coverage innovations that aim to improve health outcomes while containing cost.

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Table 1

Medicare Part D benefit design in 2014.

Benefit Period	Description	Benefit Design Cost Thresholds
Deductible Period	Beneficiaries pay 100% of drug costs until the $310 deductible threshold	$310
Coverage Gap Period	Beneficiaries reach the “coverage gap” or “donut hole”. For brand-name drugs, cost-sharing for drug costs are as follows: Beneficiaries’ copayment is 47.5% Manufacturer’s discount is 50% Drug plan’s payment is 2.5% Beneficiaries exit the coverage gap and enter the catastrophic coverage period when the sum of their out-of-pocket drug costs and manufacturers’ discounts total $4,550	$4,550
Catastrophic Coverage	Beneficiaries pay 5% of drug costs for the rest of the year	5%

Table 2

Coverage for rheumatoid arthritis drugs in Medicare Part D Stand-Alone and Medicare Advantage plans in 2013.

Drug	Plans covering drug (%)	Plans covering drug without prior authorization (%)	Plans charging percent co-insurance (%)	Mean co-insurance (%)	Average copayment* Mean (SD), Median ($)
Biologic DMARDs					
Abatacept	61	4	99	29.6	674 (36), 618
Adalimumab	100	7	100	29.7	673 (14), 684
Anakinra	30	4	100	30.0	2,993 (42), 2,982
Certolizumab	66	1	100	29.2	634 (16), 641
Etanercept	100	7	100	29.7	679 (14), 688
Golimumab	49	1	100	29.1	715 (21), 720
Infliximab	100	7	100	29.7	269 (5), 272
Rituximab	100	9	81	29.5	550 (26), 628
Toclizumab	33	2	98	29.5	332 (18), 343
Monthly average across all biologics	**71**	**5**	**97**	**29.6**	**835, 842**
Non-biologic DMARDs					
Azathioprine	100	22	11	18.1	5 (1), 5
Cyclophosphamide	94	2	13	28.4	32 (4), 18
Cyclosporine	100	0	20	25.5	33 (3), 18
Hydroxychloroquine	100	100	11	18.1	5 (1), 5
Leflunomide	100	100	11	18.1	10 (1), 6
Methotrexate	100	47	11	18.1	5 (1), 5
Minocycline	100	94	11	18.1	8 (1), 6
Penicillamine	68	68	30	30.6	114 (12), 78
Sulfasalazine	100	100	11	18.1	7 (1), 6
Monthly average across all non-biologics	**100**	**59**	**14**	**21.4**	**24, 16**

* Mean and median copayments reflect out-of-pocket costs before reaching the catastrophic phase of coverage.

Table 3

Comparison of coverage for rheumatoid arthritis drugs in Medicare Part D Stand-Alone plans (PDPs) and Medicare Advantage plans (MA-PDPs) in 2013.

Drug	Plans covering drug (%)		Plans charging percent co-insurance (%)		Mean coinsurance (%)		Average copayment** Mean, Median($)	
	PDP	MA-PD	PDP	MA-PDP	PDP	MA-PD	PDP	MA-PD
Biologic DMARDs								
Abatacept*	60	65	99.8	98.4	29.2	31.2	684, 623	649, 621
Adalimumab	100	100	99.9	99.1	29.3	31.0	668, 646	698, 718
Anakinra	22	55	100.0	99.7	29.4	31.1	2,995, 2,967	2,993, 2,998
Certolizumab	62	82	99.8	99.9	28.6	31.1	622, 596	673, 684
Etanercept	99	100	99.9	99.2	29.2	31.0	673, 650	704, 724
Golimumab	47	56	99.7	99.8	28.5	31.3	702, 673	769, 779
Infliximab*	100	100	99.9	99.3	29.3	31.0	684, 257	649, 287
Rituximab*	100	100	78.8	90.6	29.0	31.0	528, 579	641, 681
Toclizumab*	27	56	99.6	96.2	28.8	31.2	327, 322	347, 351
Monthly average across all biologics	**69**	**79**	**97**	**98**	**29.0**	**31.1**	**829, 813**	**862, 871**
Non-biologic DMARDs								
Azathioprine	100	100	11.3	7.3	17.1	25.0	4, 5	9, 8
Cyclophosphamide	93	100	13.4	8.9	28.9	25.6	31, 19	34, 26
Cyclosporine	100	100	22.1	8.8	25.5	25.5	33, 19	32, 26
Hydroxychloroquine	100	100	11.3	7.3	17.1	25.0	4, 5	8, 7
Leflunomide	100	100	11.3	7.3	17.1	25.0	9, 6	14, 11
Methotrexate	100	100	11.3	7.3	17.1	25.0	4, 4	8, 8
Minocycline	100	100	11	11.3	17.1	25.0	8, 6	8, 9
Penicillamine	69	62	34.7	10.6	31.1	25.0	121, 80	83, 75
Sulfasalazine	100	100	11	11.3	17.1	25.0	6, 5	9, 9
Monthly average across all non-biologics	**96**	**96**	**15**	**8**	**20.9**	**25.1**	**25, 17**	**23, 20**

PDP=prescription drug plan, MA-PDP=Medicare Advantage prescription drug plan, DMARD=disease-modifying anti-rheumatic drug

*Infliximab, rituximab, and tocilizumab are always administered by intravenous infusion and usually covered under Medicare Part B (rather than Part D), except under specific circumstances where administration does not occur in a physician's office.

** Mean and median copayments reflect out-of-pocket costs before reaching the catastrophic phase of coverage.

Table 4

Estimated timelines and beneficiary total copayments for biologic drugs before reaching the catastrophic phase of coverage in Medicare Part D.

Drug	Total copayments before reaching catastrophic coverage* ($)	Month beneficiaries reach coverage gap	Month beneficiaries reach catastrophic phase of coverage
Abatacept	2,761	February	March
Adalimumab	2,712	February	March
Anakinra	2,766	January	January
Certolizumab	2,755	February	March
Etanercept	2,762	February	March
Golimumab	2,754	February	March
Infliximab	2,774	March	July
Rituximab	2,759	February	March
Toclizumab	2,759	March	June

* For each drug, copayment calculations were based on average coinsurance rates charged by Part D plans.