Drug Prices and Out-of-Pocket Costs for Rheumatoid Arthritis Drugs

Statement of
Jack Hoadley, Ph.D.

Research Professor Emeritus
Health Policy Institute, McCourt School of Public Policy
Georgetown University

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Good morning, Madame Chair, Ranking Member, and Members of the Committee. My name is Jack Hoadley, and I am a Research Professor Emeritus at Georgetown University's McCourt School of Public Policy. As a long-time analyst of prescription drug issues, I have published extensively on Medicare Part D and other drug issues. I also serve as a Commissioner on the Medicare Payment Advisory Commission (MedPAC). In today's testimony I do not speak on behalf of the Commission but only for myself as an individual. I appreciate the opportunity to speak to the Committee on the issue of drug prices, specifically for drugs used to treat rheumatoid arthritis (RA), and the cost concerns experienced by Medicare beneficiaries who take these drugs.

Background

Medicare has covered outpatient drugs since the creation of Medicare Part D, which first offered coverage in 2006. But certain drugs, particularly those that must be administered by a physician (usually by injection or infusion), have always been covered by Medicare Part B. Rheumatoid arthritis drugs include medications that fall on both sides of this program divide.

Payment for a Part B drug is made to the clinician who administers the drug. Medicare typically pays the clinician 106 percent of the average sales price (ASP) for the drug, an amount that reflects the average price collected by the manufacturer net of most rebates and discounts.[1] The cost to the beneficiary is set at 20 percent coinsurance, the usual Part B coinsurance amount. For many beneficiaries, their coinsurance is covered by supplemental coverage—either privately purchased Medigap insurance, employer-sponsored retiree benefits, or by Medicaid.

Under Part D, drugs are paid by the private Part D plan in which the beneficiary is enrolled.[2] In turn, the plan's costs (which vary across phases of the benefit) are covered by a combination of a federal premium subsidy, beneficiary premiums, and federal reinsurance once a beneficiary reaches

[1] MedPAC, "Part B Drugs Payment Systems," October 2017. http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0.
[2] MedPAC, "Part D Payment System," October 2017. http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partd_final86a411adfa9c665e80adff00009edf9c.pdf?sfvrsn=0.

the catastrophic phase of the benefit. Plans may negotiate the price of the drug with the manufacturer, often obtaining rebates (discounts) that are paid to the plan but are not reflected at the point of sale. Beneficiary cost sharing varies according to the phase of the Part D benefit. For a high-cost biological, cost sharing in the initial coverage period is typically 25 percent to 33 percent. Cost sharing rises to 35 percent in the coverage gap phase (which will drop to 25 percent in 2020, when the gap if fully phased out)[3] and then drops to 5 percent in the catastrophic coverage phase. Low-income Part D enrollees are eligible for subsidies that cover most of their cost sharing.

Competition for Rheumatoid Arthritis Drugs

The market for rheumatoid arthritis drugs consists of at least ten different biological medications as well as several older traditional medications. These drugs vary in terms of their mode of action and their method of administration, and some are much newer on the market than others. Some RA drugs are approved for other health conditions as well. The drugs in this class that require administration by a clinician are covered under Medicare Part B. Those which can be self-administered are covered under Part D. This coverage split in the RA drug class has implications for the method of payment used and the determination of out-of-pocket costs. It also affects the extent to which market forces work.

At present, three biological drugs dominate the RA market. Together Enbrel, Humira, and Remicade represent over two-thirds of the RA market. Enbrel and Humira are covered under Medicare Part D and Remicade by Part B. Between 50,000 and 60,000 beneficiaries use each of these drugs, based on the most recent CMS data.[4]

The presence of multiple competing drugs in this class might be expected to help keep prices from growing rapidly. But evidence suggests otherwise. For context on the trend in drug prices, we can refer to MedPAC's annual calculation of a Part D price index.[5]

MedPAC's index data show that overall Part D drug prices rose cumulatively by 57 percent from 2007 through 2014. However, MedPAC's separate index calculation for the same timespan taking generic substitution into account was only up by a cumulative 8 percent. The difference is explained because many traditional drugs have seen patent expirations that allowed brand drug users to switch to much cheaper generic alternatives.

Notably, prices for biological drugs have grown far more rapidly—up by a cumulative 119 percent over the same years (2007-2014), compared to the 57 percent growth for all Part D drugs. These high-cost drugs include the rheumatoid arthritis drugs that are covered under Part D.

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[3] As enacted in the Patient Protection and Affordable Care Act, beneficiary coinsurance is reduced gradually until reaching 25 percent in 2020.

[4] CMS, 2015 Medicare Drug Spending Dashboard. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015Medicare.html.

[5] MedPAC, "Report to the Congress: Medicare Payment Policy," Chapter 14, Status Report on the Medicare prescription drug program (Part D), March 2017. http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf?sfvrsn=0.

It should be noted that these price indexes exclude manufacturer rebates. CMS reports that rebates have increased generally over this same period (though data are not available for specific drugs or drug classes), so price increases net of rebates may be somewhat lower.

Cost to Medicare and the Beneficiary for Rheumatoid Arthritis Drugs

Looking specifically at the costs of the three most common RA drugs, they are expensive for both the Medicare program and the beneficiaries who take these drugs. And the costs continue to rise.

In 2015, Remicade was one of the top five Part B drugs in terms of annual costs to Medicare—at $1.2 billion.[6] An average user of Remicade had $4,280 in out-of-pocket costs over the course of a year. As noted before, many beneficiaries have these costs are covered by supplemental coverage or Medicaid. Total spending on Remicade rose 34 percent between 2011 and 2015 or about 8 percent per year.

On the Part D side, Humira had the largest market share and a total cost for Medicare beneficiaries of $1.6 billion in 2015 (although Part D spending totals are calculated before the rebate discounts arranged between manufacturers and plans).[7] In terms of total dollar volume, it represented the 10th costliest Part D drug. An average user of Humira incurred $1,588 in out-of-pocket costs for the year. This amount is less than the average for Remicade because cost sharing drops to 5 percent after a beneficiary exceeds the catastrophic spending threshold. Furthermore, a beneficiary taking a full dose of Humira for an entire year would incur almost $5,000 in out-of-pocket Part D costs for that drug.[8] Total spending for Humira has more than tripled—up 224 percent from 2011 to 2015. This reflects both a 79 percent increase in the unit price combined with a similar increase in volume.

The numbers for Enbrel are similar: $1.4 billion in total volume in 2015 and $1,590 in a year's out-of-pocket costs for the average user.[9] Total spending for Enbrel more than doubled—up 144 percent from 2011 to 2015. Like Humira, its price rose about 80 percent, but it experienced more modest volume growth.

It is worth noting that price increases have been more modest on the Part B side, in part because most rebates are incorporated into the Part B pricing system and in part because the ASP system may be more effective in controlling price increases than the tools available to Part D plans.

Biosimilars: Potential for Savings and Barriers

Over the last decade, one of the largest checks on drug spending growth has been the emergence of generic alternatives for many of the most used traditional drugs, together with the absence of significant new medications to compete with these drugs. A key question is whether biosimilars can play the same role in bringing down prices for biologicals, such as those that treat RA. Many

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[6] CMS, 2015 Medicare Drug Spending Dashboard.
[7] CMS, 2015 Medicare Drug Spending Dashboard.
[8] J Hoadley, J Cubanski, and T Neuman, "It Pays to Shop: Variation in Out-of-Pocket Costs for Medicare Part D Enrollees in 2016," Kaiser Family Foundation, December 2015. https://www.kff.org/medicare/issue-brief/it-pays-to-shop-variation-in-out-of-pocket-costs-for-medicare-part-d-enrollees-in-2016/.
[9] CMS, 2015 Medicare Drug Spending Dashboard.

observers anticipate that prices should drop, perhaps in the range of 35 percent, as biosimilars penetrate the RA market.[10] Notably, even if prices drop, total spending on biologicals is likely to grow as more of these medications enter the market.

On the Part B side, two biosimilars for Remicade have entered the market. But their impact to date has been modest. When the first biosimilar (Inflectra) was launched in 2017, its price to Medicare was about 20 percent higher than the price of Remicade. The price of Remicade, meanwhile, rose by 4 percent between the first two quarters it had a competitor.[11] Public data are not available yet to determine whether the launch of a second competitor to Remicade has had a different effect.

In its report to Congress in June 2017, MedPAC made a set of recommendations with the goal of moderating Part B prices. One item in that set specifically focuses on biosimilars by modifying the ASP system to "require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars."[12] Today the original biologic (the reference biologic) has one code and all biosimilars are combined into a second billing code. The idea behind consolidating to a single code is to increase price competition. Providers would be paid based on the average price (weighted by volume) across the competing drugs, providing a stronger incentive to use the lower-price competitor. CMS has proposed a move in the opposite direction—to create separate billing codes for each of the biosimilars that competes with a reference biologic. If this proposed policy is finalized, it could reduce the pressure among biosimilar manufacturers to compete for lower prices.

The MedPAC recommendations also calls on Congress to "create and phase in a voluntary Drug Value Program" designed to encourage lower prices by permitting private vendors to negotiate and share any savings with the participating providers.[13] Savings would be shared with beneficiaries in the form of lower cost sharing and with the Medicare program.

No biosimilars have reached the market yet for the two major Part D RA drugs. A biosimilar for Humira has been approved by the Food and Drug Administration (FDA), but entry into the U.S. market has been delayed until 2023 by a court settlement between the biosimilar manufacturer and the manufacturer of Humira. Similarly, a biosimilar for Enbrel has FDA approval, but patent litigation has delayed its market launch.

The future for RA and other biosimilars depends on the drugs reaching the market and gaining broad acceptance. Their timely launch on the market will rely on resolving patent cases and other legal issues. Once launched, the path to widespread acceptance and substantial market penetration will rely on several factors: (1) the establishment of interchangeability status by the FDA; (2) state laws that determine whether pharmacies can substitute biosimilars with the prescriber's approval—as is done for traditional drugs; (3) general acceptance of the biosimilars by both clinicians and their

[10] A Mulcahy, Z Predmore, and S Mattke, "The Cost Savings Potential of Biosimilar Drugs in the United States," RAND Corporation, 2014. https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.
[11] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," Chapter 2, Medicare Part B drug payment policy issues, June 2017, http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0.
[12] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," Chapter 2, Medicare Part B drug payment policy issues, June 2017.
[13] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," Chapter 2, Medicare Part B drug payment policy issues, June 2017.

patients; and (4) further research showing that patients who switch to biosimilars do so without problems. Several biosimilars for RA drugs are on the market in Europe, and some early evidence shows success in having most patients make the switch without any adverse consequences.[14]

Additional Ways to Protect Beneficiaries

The most important steps to achieving lower costs for biologicals, including expensive RA drugs, are likely to be those that increase the role of biosimilars in the market. But there are other measures that can also bring savings in both Part B and Part D for beneficiaries and the Medicare program.

The Part B ASP system that was put in place by the Medicare Modernization Act of 2003 has had some success in moderating price increases compared to the previous system. Nevertheless, prices for some drugs have gone up well beyond inflation. Earlier, I discussed the set of MedPAC recommendations addressing Part B drugs that were published in the Commission's June 2017 report to Congress.[15] In addition to calling for common billing codes for biosimilars and a reference biologic, the Commission recommended other modifications to the ASP system. They are (1) a requirement that all manufacturers submit ASP data with penalties for failure to report; (2) a reduction in wholesale acquisition cost (WAC)-based payment to WAC plus 3 percent; and (3) a requirement that manufacturers pay a rebate when ASP increases exceed an inflation benchmark (both beneficiary cost sharing and the ASP add-on would be based on the inflation-adjusted ASP). As noted above, the Commission linked these recommendations to creation of a new voluntary Drug Value Program to create more opportunities for achieving lower prices for Part B drugs.

According to the MedPAC report, these recommendations represent a balanced approach to improving the payment system for Part B drugs, including RA drugs like Remicade. If enacted and implemented, these measures could lower Part B drug prices in a way that should save money for both beneficiaries and the Medicare program.[16]

Just as in Part B, Part D presents opportunities for reducing costs. In June 2016, MedPAC approved a set of recommendations for Part D.[17] In January of this year, the Commission approved an additional recommendation that will be published in its upcoming March report to the Congress.

The recommendations in the June 2016 MedPAC report included multiple items that should be viewed together as a package. I highlight here the items that are most relevant to high-priced RA drugs. The first set of recommendations calls for reducing Medicare's individual federal reinsurance subsidy to create a stronger incentive for Part D plans to negotiate the best possible prices, especially for high-priced drugs that typically drive costs into the catastrophic phase of the benefit. It also calls

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[14] Center for Biosimilars, "4 Studies Address Successes, Failures, and Strategies in Non-Medical Biosimilar Switching," November 7, 2017. http://www.centerforbiosimilars.com/conferences/acr-2017/4-studies-address-successes-failures-and-strategies-in-nonmedical-biosimilar-switching.

[15] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," Chapter 2, Medicare Part B drug payment policy issues, June 2017.

[16] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," Chapter 2, Medicare Part B drug payment policy issues, June 2017.

[17] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," Chapter 6, Improving Medicare Part D, June 2016. http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf?sfvrsn=0.

for eliminating enrollee cost sharing in the catastrophic phase while also excluding manufacturers' discounts in the coverage gap from the calculations of enrollees' true out-of-pocket spending. The latter measures have the potential to create significant savings for beneficiaries who take drugs like Enbrel or Humira. Another set of recommendations would modify the Part D Low-Income Subsidy to strengthen the incentive for subsidized beneficiaries to select generics and biosimilars. The final set includes several measures to provide Part D plans more tools to manage their formularies and thus reduce overall spending.

As noted above, the 2016 MedPAC recommendations were supplemented by an additional recommendation approved in January 2017. It states that "The Congress should change Part D's coverage gap discount program to require manufacturers of biosimilar products to pay the coverage gap discount by including biosimilars in the definition of applicable drugs; and exclude biosimilar manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending." The idea of this change is to level the competitive playing field between biosimilars and reference biologics. Today only the original biologics have a required manufacturer discount in the coverage gap, which has the effect of making biosimilars noncompetitive.

The Commission's Part D recommendations address potential program improvements that go beyond the specific RA drugs under consideration in this hearing. If enacted, however, they should help lower costs for beneficiaries who take RA drugs.

The Bottom Line

Today, the biological medications used to treat rheumatoid arthritis are expensive for both the beneficiary and the taxpayer. Biosimilars bring the potential for a more competitive market and lower prices. But current policies create barriers to accomplishing these ends. In addition to considering actions that could lower those barriers, the Congress should consider other policy measures that could lower the cost of RA drugs for Medicare and its beneficiaries.