Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

DATA SNAPSHOT

May 2025 | OEI-05-23-00520

Most Medicare Part D Plans' Formularies Included Humira Biosimilars for 2025

HHS Office of Inspector General
HIGHLIGHTS

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Why OIG Did This Review

- Humira, a biologic drug used to treat autoimmune conditions such as rheumatoid arthritis, is one of the best-selling prescription drugs in the world. In the United States, it has an annual list price of approximately $90,000. In 2022, it cost the Part D program and enrollees $5.4 billion before accounting for rebates and other price concessions.
- The launch of Humira biosimilars (which are highly similar to Humira, with no clinically meaningful differences) has been anticipated as an opportunity to lower biologic drug costs through competition. However, if Part D plans' formularies restrict access to Humira biosimilars, competitive pressure—and its potential effects on lowering drug costs—may be limited.
- Previous OIG work found that many Part D formularies did not cover biosimilars available for other expensive biologic drugs. OIG also found that this lack of formulary coverage could limit wider biosimilar use and any potential savings for Medicare Part D.

What OIG Found

Part D plans' formulary coverage of Humira biosimilars increased substantially between 2024 and 2025. Nearly all Part D Prescription Drug Plans (PDPs) (96 percent), and 88 percent of Medicare Advantage Prescription Drug (MAPD) plans, covered at least 1 of the 10 available Humira biosimilars on their 2025 formulary—including some plans that covered Humira biosimilars only and not Humira. This represents substantial growth in formulary coverage from 2024, when only 65 percent of PDPs and 52 percent of MAPD plans covered at least one of Humira's biosimilars. However, 1 percent of PDP enrollees and 10 percent of MAPD enrollees were in plans that covered Humira only in 2025, which in effect prevents these enrollees' use of Humira biosimilars.

Almost none of the formularies that covered Humira and its biosimilars used preferential tier placement to encourage biosimilar use. Ninety-nine percent of these formularies placed Humira and its biosimilars on the same cost-sharing tier. Likewise, these formularies either applied or did not apply utilization management requirements (i.e., prior authorization or step therapy) to both Humira and covered biosimilars. This means that the formularies did not use such tools to encourage the use of biosimilars, nor to discourage their use.

What OIG Concludes

Most—but not all—Part D plans covered Humira biosimilars in 2025. This increase in coverage is a positive trend, as both the Medicare Payment Advisory Commission and the Federal Trade Commission have raised concerns about the anticompetitive effects of limited biosimilar formulary coverage. OIG previously recommended that CMS monitor biosimilar coverage on formularies to identify any concerning trends, such as exclusion of biosimilars from formularies or preferential treatment for reference products like Humira. In response, CMS assessed whether 2024 Part D formularies included available biosimilars in addition to their reference products. We encourage CMS to continue this formulary monitoring.

Primer: Biosimilars and Part D Formulary Coverage

Biologic drugs like Humira (usually large, complex molecules produced in a living system) are some of the most expensive drugs available.[1]

A **biosimilar** is a biologic that is highly similar to and has no clinically meaningful difference from an existing Food and Drug Administration (FDA)-approved biologic (i.e., the biosimilar's "reference product").[2] Biosimilars compete with their reference products and are often less expensive.[3] Nine Humira biosimilars launched in 2023, with a tenth becoming available in 2024.[4]

Part D Prescription Drug Plans. Enrollees in traditional Medicare get their Part D prescription drug coverage from stand-alone prescription drug plans (PDPs), while Medicare Advantage includes prescription drug coverage through Medicare Advantage prescription drug (MAPD) plans. Our 2025 analysis includes 524 PDPs and 4,663 MAPD plans.

Formularies. Each PDP or MAPD plan has a formulary, which lists the drugs that the plan covers and organizes them into tiers with different cost-sharing requirements. Plans use formularies to encourage or discourage the use of certain covered drugs and to control costs. The same formulary may be used by multiple PDPs and/or MAPD plans. Our 2025 analysis includes 353 unique formularies.

Plans' formularies can **exclude drugs**—including biosimilars, like those for Humira—to in effect prevent their enrollees from using them.[5, 6]

Formulary coverage of Humira only

Effectively prevents biosimilar use

Formulary coverage of Humira + biosimilars

Enables biosimilar use

Formulary coverage of biosimilars only

Effectively requires biosimilar use

Plans can also use other **formulary tools** to encourage use of a covered drug or discourage the use of its competitors. For example, Part D plans can:

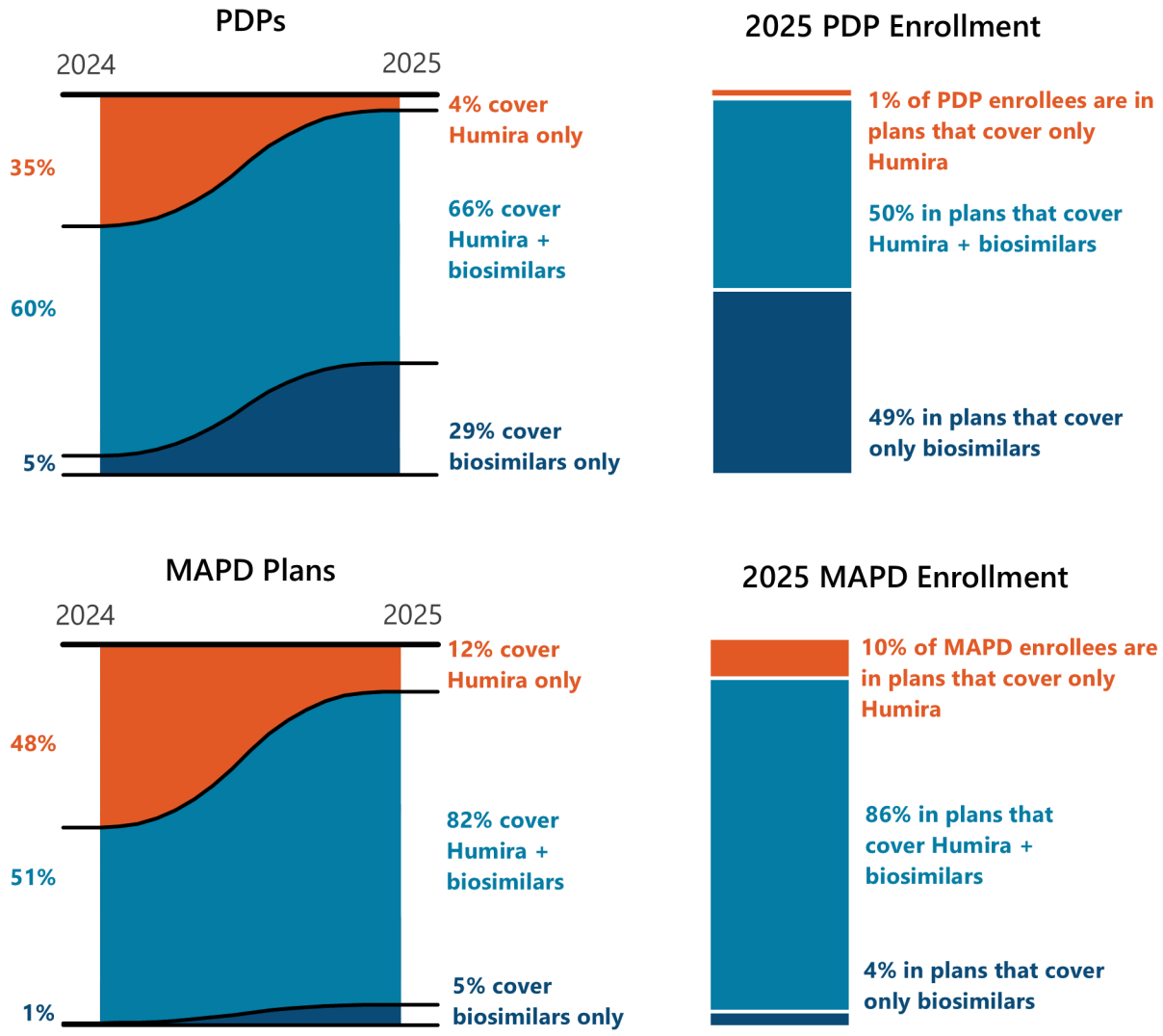
- Put a drug on a **lower formulary tier**—with lower enrollee cost-sharing—than its competitors to promote its use.[7]
- Implement **utilization management** requirements such as prior authorization and step therapy for a drug's competitors.
    - **Prior authorization** requires prescribers to obtain approval from the Part D plan before it will cover a specific drug; implementing prior authorization for Humira, but not its biosimilars, would make it easier for an enrollee to access the biosimilar.
    - **Step therapy** typically requires beneficiaries to first try a less expensive drug before moving to a more expensive drug; a plan could implement step therapy for Humira that required enrollees to first try a less expensive Humira biosimilar before getting approval to use Humira.

Formulary Review. The Center for Medicare & Medicaid Services (CMS) conducts an annual formulary review to ensure that Part D plans' formularies align with best practices, provide sufficient access to a range of drugs, and do not discourage the enrollment of certain enrollees.[8] At a minimum, formularies must cover commonly needed drugs and generally must offer at least two different drugs in each drug class and category.[9] The formulary review process does not include an assessment of drugs' costs to enrollees or the Medicare program because CMS cannot generally intervene in the negotiations between drug manufacturers and plan sponsors; require a particular formulary; or set a price structure for the reimbursement of covered Part D drugs.[10]

Part D Plans' Coverage of Humira Biosimilars

Part D plans' formulary coverage of Humira biosimilars increased substantially between 2024 and 2025. Nearly all Part D PDPs (96 percent) and 88 percent of MAPD plans included at least one of the 10 available Humira biosimilars on their 2025 formulary. This represents substantial growth in Humira biosimilar formulary coverage compared to the previous year, when only 65 percent of PDPs and 52 percent of MAPD plans covered any Humira biosimilar. Because plan size can vary, we also analyzed the proportion of enrollees in these plans. Overall, 99 percent of enrollees in PDPs and 90 percent of enrollees in MAPD plans had access to at least one Humira biosimilar in 2025. See Exhibit 1 below for the change in plans' Humira biosimilar coverage over time and 2025 enrollment in these plans.

Exhibit 1. Both MAPD plans and PDPs have increased coverage of Humira biosimilars, with at least 90 percent of enrollees in each plan type having access to a Humira biosimilar in 2025.



Source: OIG analysis of CMS Part D formulary data, landscape files, and enrollment information (2024-2025).
Note: Totals do not always add up to 100 percent due to rounding.

Some plans covered only the Humira biosimilars. Many enrollees were in plans that **covered Humira biosimilars only in 2025, which in effect requires the use of Humira biosimilars**. This type of exclusive biosimilar coverage can more effectively drive biosimilar use than covering a Humira biosimilar in addition to Humira.[11] A much higher proportion of PDP enrollees (49 percent) were in plans that used such formularies than MAPD enrollees (4 percent).

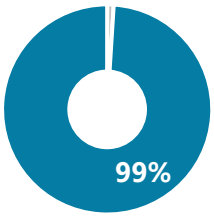
Some plans still restricted enrollees' access to the Humira biosimilars. Some enrollees were in plans that still **covered Humira only in 2025, which in effect prevents the use of its biosimilars**. A higher proportion of MAPD enrollees (10 percent) were in plans that used such formularies than PDP enrollees (1 percent).[12]

See Appendix A for additional details about plans and enrollment in 2024 and 2025.

Formularies Used by Plans

We analyzed the unique Part D formularies used by PDPs and MAPD plans to determine whether they used formulary tools such as differences in tier placement, prior authorization, or step therapy to encourage Humira biosimilar use. We also assessed whether Humira biosimilar formulary coverage differed by the drugs' characteristics.

Almost none of the formularies that covered Humira and its biosimilars used preferential tier placement to encourage biosimilar use. The vast majority of these formularies placed Humira and its biosimilars on the same cost-sharing tier. Likewise**,** these formularies either applied or did not apply utilization management requirements (i.e., prior authorization or step therapy) to both Humira and covered biosimilars. This means that the formularies did not use such tools to encourage the use of Humira biosimilars, nor to discourage their use.

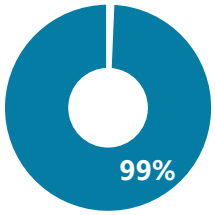


Almost all of these formularies included both Humira and its biosimilars on the **same cost-sharing tier**.

- Ninety-nine percent of these formularies placed Humira and its biosimilars on the same cost-sharing tier—usually on a specialty tier with enrollee coinsurance between 25 and 33 percent, where differences in enrollees' out-of-pocket (OOP) spending for a prescription depends on the plan-negotiated prices for these products. For enrollees who regularly use a Humira biosimilar or Humira on a specialty tier to treat a chronic condition, total annual OOP spending would likely be limited by the $2,000 cap on Part D OOP spending that took effect in 2025.[13]

- A few plans used formularies that placed a Humira biosimilar on a lower cost-sharing tier than Humira. For example, some plans used a formulary that placed one Humira biosimilar on a preferred brand tier, with lower cost-sharing in the form of a fixed-dollar copayment, and all other covered Humira biosimilars on the same specialty tier as Humira with percentage-based

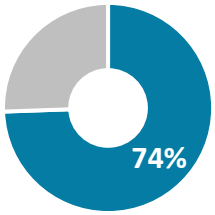
coinsurance. This placement creates an incentive for enrollees to use the one Humira biosimilar with the lowest cost-sharing.



Almost all of these formularies **either used or did not use utilization management requirements, such as prior authorization or step therapy**, for both Humira and covered biosimilars.

- Specifically, for 99 percent of these formularies, prior authorization and step therapy requirements either applied or did not apply to both Humira and covered biosimilars. Most formularies did require prior authorization for both Humira and covered biosimilars, but typically did not require step therapy for either.
- We did not assess whether the specifics of formularies' prior authorization policies differed for Humira and covered biosimilars. A formulary's prior authorization policy for Humira could specify that enrollees must try a covered biosimilar before receiving approval for a Humira prescription.

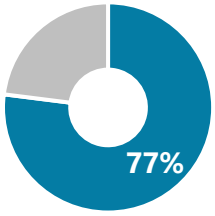
Seventy-four percent of formularies with Humira biosimilars included one of the six available interchangeable options, which a pharmacist can dispense instead of Humira.



Pharmacists can substitute Humira biosimilars that FDA has designated as "interchangeable" for a Humira prescription without contacting the prescriber, as is allowed for small-molecule brand and generic drugs.[14] Any formulary that covers one of these six interchangeable options in addition to Humira provides an additional opportunity for an enrollee to use the biosimilar rather than Humira.

FDA has recently supported considering all biosimilars to be interchangeable with their reference products—a change that would allow pharmacists to fill Humira prescriptions with any of the available Humira biosimilars.[15]

Seventy-seven percent of formularies with Humira biosimilars included an option that, like Humira, reduces injection site pain.



The most prescribed version of Humira has two characteristics that reduce injection site pain:

- Citrate-free formulation
- High concentration[16]

Most formularies included at least one of the six Humira biosimilars available in a citrate-free, high-concentration version. Patients and prescribers may be more willing to use Humira biosimilars if they are available with these characteristics.[17] All formularies that exclusively covered Humira biosimilars—and therefore in effect prevented the use of Humira—included a citrate-free, high-concentration version.

Primer: List Prices and Rebates

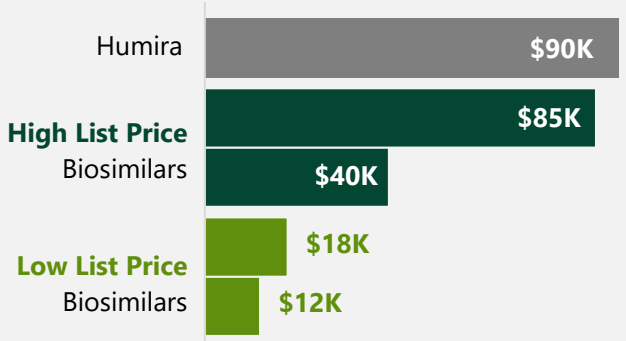
Manufacturer List Prices. List prices are manufacturers' published wholesale prices. They do not represent the transaction prices paid by Part D plans or include retroactive rebates paid by manufacturers. Manufacturers can offer their drugs at a low list price, likely with little or no rebate. Alternately, manufacturers may offer high list price drugs which can be paired with a rebate that results in a lower net cost to Part D plans than the published list price.[18]

Rebate Dynamics and Price Competition. There have been longstanding concerns about the effects of high list price, highly rebated drugs on drug price competition and Medicare Part D spending.[19] The Federal Trade Commission has noted that rebates for reference products like Humira may prevent competition from lower-cost biosimilars.[20] Specifically, agreeing to exclusively cover a high list price drug with a rebate may be more profitable for Part D plans than including lower-price competitors with little (or no) rebate on their formularies. This can lead to the exclusion of drugs like biosimilars from formularies, which limits enrollee access and thus reduces the competitive pressure to lower prices.[21] However, changes to the Part D benefit that went into effect in 2025—such as plans' increased liability for drug costs—have likely altered these incentives in ways that are yet to be determined.[22]

Formulary Coverage by List Price

To compete with Humira, biosimilar manufacturers have taken a variety of pricing approaches. An annual course of treatment for rheumatoid arthritis with Humira has a list price of $90,000, but the net cost to the Part D program would likely be lower after accounting for rebates.[23] Some Humira biosimilar manufacturers take a similar approach and offer their biosimilars at a high list price, which may come with a rebate, while others offer their biosimilars at a much lower list price than Humira. Some manufacturers use both pricing strategies for the same Humira biosimilar to appeal to different customers.[24, 25] We classified Humira biosimilars as either high list price or low list price according to their list prices relative to that of Humira for an annual course of rheumatoid arthritis treatment. See Exhibit 2 for the range of "high" and "low" Humira biosimilar list prices.

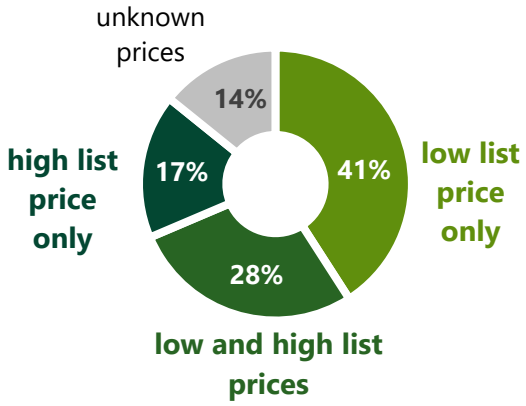
Exhibit 2. The range of list prices for an annual course of rheumatoid arthritis treatment varied among Humira biosimilars.



Source: OIG analysis of September 2024 Wholesale Acquisition Costs.
Note: List prices do not represent the transaction prices paid by Part D plans or include retroactive rebates paid by manufacturers.

We found that formularies varied in whether they covered Humira biosimilars with low list prices, high list prices, or both. Of the formularies that covered Humira biosimilars, 41 percent covered only low list price biosimilars, while 28 percent covered both low list price biosimilars and high list price biosimilars. Seventeen percent of formularies covered only high list price Humira biosimilars. We could not determine whether the remaining 14 percent of formularies covered high or low list price Humira biosimilars due to data limitations.[26] See Exhibit 3.

Exhibit 3. Formularies varied in whether they included low list price Humira biosimilars, high list price Humira biosimilars, or both.



Source: OIG analysis of Part D 2025 formulary data and September 2024 Wholesale Acquisition Costs.

What OIG Concludes

Part D plans' coverage of Humira biosimilars has grown substantially since 2024, and most plans' formularies included Humira biosimilars in 2025. This is a positive trend, as multiple groups have noted that biosimilar formulary coverage is critical for drug price competition to lower prescription drug costs for Medicare. For example, the Medicare Payment Advisory Commission has noted that Part D plans' coverage of biosimilars will be key to generating the competitive pressure necessary to lower already high—and rising—biologic drug prices.[27] Furthermore, expensive biologic drugs like Humira are excluded by law from Medicare Part D drug price negotiations when biosimilar competitors are available. Thus, biosimilars for these drugs must be included on formularies to create meaningful competition for manufacturers of reference products.

OIG previously recommended that CMS monitor biosimilar coverage on formularies to identify any concerning trends, such as exclusion of biosimilars from formularies or preferential treatment for reference products like Humira.[28] In response to this recommendation, CMS assessed whether 2024 Part D formularies included available biosimilars in addition to their reference products. CMS has also taken additional steps to encourage biosimilar formulary coverage, such as making it easier for plans to replace reference products with newly available biosimilars beginning in 2025.[29] We encourage CMS to continue monitoring plans' formularies to determine whether they include these alternatives to expensive biologic drugs.

Methodology

We determined the extent to which Medicare Part D PDPs' and MAPD plans' approved 2024 and 2025 formularies covered Humira and its biosimilars.[30, 31]

- We used formulary data from CMS's Health Plan Management System (HPMS) to identify formularies and covered biologic drugs.
- We used First DataBank National Drug Data as of September 2024 to identify the drug product information—including pricing—for Humira and its biosimilars.
- We used the FDA Purple Book to determine which Humira biosimilars were interchangeable.
- We used information from HPMS and the 2024 and 2025 Part D landscape files from CMS to identify unique PDPs and MAPD plans.
- We used information from CMS's Integrated Data Repository to determine the number of enrollees in PDPs and MAPD plans in January 2024 and January 2025.

To evaluate formulary coverage of Humira and its biosimilars, we took the following steps:

- We calculated the percentage of unique PDPs and MAPD plans using formularies that covered Humira and/or its biosimilars in 2024 and 2025, as well as the percentage of enrollees in those plans.
- Our analysis included 388 unique formularies in 2024 and 353 unique formularies in 2025. In both years, all formularies used by PDPs and MAPD plans covered (1) only Humira; (2) Humira and a Humira biosimilar; or (3) only a Humira biosimilar.

- For 2025 formularies that covered Humira and a Humira biosimilar, we calculated the percentage that (1) placed them on different formulary tiers and (2) had a step therapy or prior authorization requirement for Humira, but not its biosimilars (or vice versa). We did not analyze the details of the prior authorization requirements.
- For each unique formulary, we also examined the characteristics of the covered Humira biosimilars (e.g., interchangeability, concentration, and manufacturer list price).

We compared the list prices for Humira and its biosimilars on the basis of the strength and concentration used for treatment of rheumatoid arthritis. To compare these list prices, we took the following steps:

- We used Wholesale Acquisition Cost (WAC) prices from First DataBank to calculate the list price per 40mg syringe, vial, or autoinjector (unit).
- We categorized Humira biosimilars with per-unit list prices at least 80 percent lower than Humira as "low list price" and the rest as "high list price."
- We calculated annual list prices by multiplying the list price per unit by 26 (the average number of units used to treat rheumatoid arthritis over the course of a year).
- We also calculated the percentage of formularies covering low- and high-cost Humira biosimilars.

Limitations

This study evaluated Humira biosimilar inclusion on formularies only, and not the use of these biosimilars by enrollees. Additionally, the WAC prices we used to categorize Humira biosimilars as having "high" or "low" list prices may be different from the prices negotiated by Part D plans with manufacturers and do not account for retroactive rebates paid by manufacturers. We did not assess whether formularies specify prior authorization requirements differently for Humira and covered biosimilars (e.g., whether requirements to document previous treatments or current conditions differ). Finally, Part D plans may update their formularies over the course of the plan year. Our analysis does not reflect any of these mid-year changes.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Appendix

Appendix A: Humira Biosimilar Formulary Coverage by Plan and Plan Enrollment (2024-2025)

Table A1: PDPs

Formulary Coverage	2024 Plans		2025 Plans		2024 Enrollees		2025 Enrollees	
Humira Only	234	(34.6%)	22	(4.2%)	10,381,565	(59.1%)	206,800	(1.1%)
Humira and Biosimilar	408	(60.4%)	348	(66.4%)	6,374,642	(36.3%)	9,099,861	(50.2%)
Biosimilar Only	34	(5.0%)	154	(29.4%)	824,642	(4.7%)	8,809,750	(48.6%)
TOTALS	676		524		17,580,849		18,116,411	

Table A2: MAPD Plans

Formulary Coverage	2024 Plans		2025 Plans		2024 Enrollees		2025 Enrollees	
Humira Only	2,308	(48.1%)	576	(12.4%)	8,386,419	(32.4%)	2,787,045	(10.3%)
Humira and Biosimilar	2,463	(51.3%)	3,835	(82.2%)	17,420,909	(67.2%)	23,240,347	(85.7%)
Biosimilar Only	30	(0.6%)	252	(5.4%)	104,329	(0.4%)	1,093,952	(4.0%)
TOTALS	4,801		4,663		25,911,657		27,121,344	

Source: OIG analysis of CMS Part D formulary data, landscape files, and enrollment information (2024-2025).
Notes: Differences in the percentage of plans covering a Humira biosimilar and the percentage of enrollees in plans covering a Humira biosimilar are the result of variation in plan size. Totals do not always add up to 100 percent due to rounding.

Endnotes

[1] Kaiser Permanente Business, "Biosimilars can significantly reduce employer pharmacy costs. Are you missing out?," October 24, 2023. Accessed on November 8, 2024.

[2] The Biologics Price Competition and Innovation Act (BPCIA), part of the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biosimilars to introduce competition and lower prices for biologics. Under BPCIA, the FDA may approve a biosimilar once its manufacturer demonstrates that the biosimilar is "highly similar" to the already approved biologic reference product and that there are no "clinically meaningful differences" between the reference product and biosimilar. P.L. 111–148, Title VII, §§ 7001-7003, and 42 U.S.C. § 262(i).

[3] National Council of State Legislatures, *Brief: Decreasing Drug Costs Through Generics and Biosimilars*, January 21, 2022. Accessed on December 18, 2024.

[4] While FDA approved the first Humira biosimilar in 2016, patent litigation and patent dispute settlements prevented these potentially more affordable biologic drugs from launching in the U.S. market until 2023. While the first Humira biosimilar, Amjevita, became available in January 2023, the remaining nine Humira biosimilars became available in July 2023 or later. FDA, "FDA approves Amjevita, a biosimilar to Humira," September 23, 2016. Accessed on September 6, 2023. See also Mike Zhai, Ameet Sarpatwari, and Aaron Kesselheim, "Why Are Biosimilars Not Living up to Their Promise in the US?," *AMA Journal of Ethics*, August 2019, p. 671. Accessed on June 15, 2021.

[5] Nitzan Arad, et al., Duke-Robert J. Margolis Center for Health Policy, *Realizing the Benefits of Biosimilars: Overcoming Rebate Walls*, March 9, 2022, p. 6. Accessed on October 3, 2024.

[6] Enrollees can use an exceptions and appeals process to request coverage of drugs excluded from their plan's formulary, but this requires them to take administrative actions and does not guarantee that they can get the drugs. Enrollees could also opt to pay out of pocket for noncovered drugs.

[7] According to CMS, tier 1 should be the lowest cost-sharing tier available to beneficiaries, and any subsequent tiers should be higher cost-sharing tiers in ascending order. CMS, *Medicare Prescription Drug Benefit Manual*, Ch. 6, § 30.2.7. Accessed on November 3, 2024.

[8] CMS, *Medicare Prescription Drug Benefit Manual*, Ch. 6, § 30.2.7. Accessed on November 3, 2024.

[9] 42 CFR § 423.120(b)(2).

[10] There is an exception to this prohibition for the small number of single-source drugs that are subject to Medicare Part D drug price negotiations. The Social Security Act, 1860D-11(i).

[11] In the commercial market, exclusive biosimilar formulary coverage has been a strong driver of biosimilar use. See STAT, "Thanks to CVS, a biosimilar version of AbbVie's Humira is grabbing huge market share," April 15, 2024. Accessed on October 3, 2024.

[12] While enrollees can opt into a Part D plan with biosimilar coverage during set enrollment periods, they have limited opportunities to switch to a plan covering a biosimilar later in the plan year. See CMS, "Joining a plan." Accessed on October 3, 2024.

[13] Inflation Reduction Act of 2022. P.L. No. 117-169, § 11201(a).

[14] Biosimilars can be deemed "interchangeable" by FDA if the manufacturer can demonstrate that the biosimilar produces the same clinical result as the reference product in any given patient. This designation primarily affects biosimilar use in the pharmacy setting, as in most States, pharmacists can substitute an interchangeable biosimilar for its reference product without involving the prescriber. 42 U.S.C. § 262(k)(4).

[15] For example, FDA has made it easier for manufacturers to achieve an interchangeable designation and has also supported proposals to consider all biosimilars to be interchangeable. FDA, *Considerations in Demonstrating Interchangeability With a Reference Product: Update*, June 2024. Accessed on October 3, 2024. See also Endpoints News, "FDA is ready to eliminate the

interchangeability designation for biosimilars," April 15, 2024. Accessed on October 3, 2024. See also U.S. Department of Health and Human Services, *Fiscal Year 2025 Budget in Brief*, p. 83. Accessed on April 17, 2025.

[16] Vizient, "Biosimilars are the Same, Yet Different, and That May Impact Utilization," January 25, 2023. Accessed on March 17, 2025.

[17] Cardinal Health, *2024 Biosimilars Report: Insights on a pivotal year of evolution and expansion*, 2024, p. 23. Accessed on October 24, 2024.

[18] Congressional Research Service, *Negotiation of Drug Prices in Medicare Part D*, May 23, 2022, p. 1. Accessed on October 3, 2024.

[19] GAO, *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending* (GAO-23-105270), September 5, 2023, pp. 2-3. Accessed on November 26, 2024.

[20] Federal Trade Commission, *Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products*, June 16, 2022. Accessed on October 4, 2024.

[21] For example, manufacturers can withdraw rebates for a reference product like Humira—or for a bundle of products—if a biosimilar competitor is added to the formulary. Without widespread adoption of the biosimilar, the savings from the lower net cost biosimilar may not be enough to offset the loss of rebates for the more widely used reference product (or bundle of products). Nitzan Arad, et al., Duke-Robert J. Margolis Center for Health Policy, *Realizing the Benefits of Biosimilars: Overcoming Rebate Walls*, March 9, 2022, pp. 7-10. Accessed on October 3, 2024.

[22] Milliman, *A primer on Medicare Part D prescription drug rebates: Insights into the possible impact of the Inflation Reduction Act*, p. 4, September 29, 2023. Accessed on November 21, 2024.

[23] Research indicates that rebates for Humira were substantial before biosimilar competition and increased with the launch of the first Humira biosimilars. The exact amount of these rebates is not publicly disclosed. Stanton Mehr, "Sustaining competition for biosimilars on the pharmacy benefit: Use it or lose it," *Journal of Managed Care and Specialty Pharmacy*, June 2024, p. 601. Accessed on November 5, 2024.

[24] Some manufacturers offer an unbranded version with a low list price and a branded version with a higher list price and a large rebate. Others offer both high and low list prices for the same branded drug. See Mariam Sunny and Patrick Wingrove, "Boehringer launches 81% discounted biosimilar of AbbVie's Humira," *Reuters*, October 3, 2023. Accessed on October 4, 2024. See also Fierce Pharma, "Amgen's Humira biosimilar Amjevita hits the market with 2 different list prices," January 31, 2023. Accessed on October 4, 2024.

[25] This includes some co-branded versions of Humira biosimilars launched by manufacturers in partnership with pharmacy benefit managers, such as CVS Caremark and Express Scripts. CVS, *CVS Health launches Cordavis*, August 23, 2023.

[26] The remaining 14 percent of formularies included a single Humira biosimilar available at both high and low list prices (e.g., a branded Humira biosimilar with two different list prices). Due to the structure of Part D formulary data, we could not determine whether these formularies covered the high or low list price version of these Humira biosimilars, and therefore could not categorize the formularies as covering high list price Humira biosimilars, low list price Humira biosimilars, or both.

[27] The Medicare Payment Advisory Commission (MedPAC), *"Chapter 11: The Medicare prescription drug program (Part D): Status report," Report to the Congress: Medicare Payment Policy*, March 2024, pp. 335-337. Accessed on October 4, 2024.

[28] OIG, *Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use* (OEI-05-20-00480), March 2022.

[29] 89 Fed. Reg. 30448, 30451 (April 23, 2024).

[30] Our analysis includes Special Needs Plans. It excludes employer group plans, demonstration projects, PACE plans, and plans only operating in U.S. territories.

[31] Enrollees chose plans that used the 2025 formularies during calendar year (CY) 2025 open enrollment, while the 2024 approved formularies were in use at the beginning of CY 2024.

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