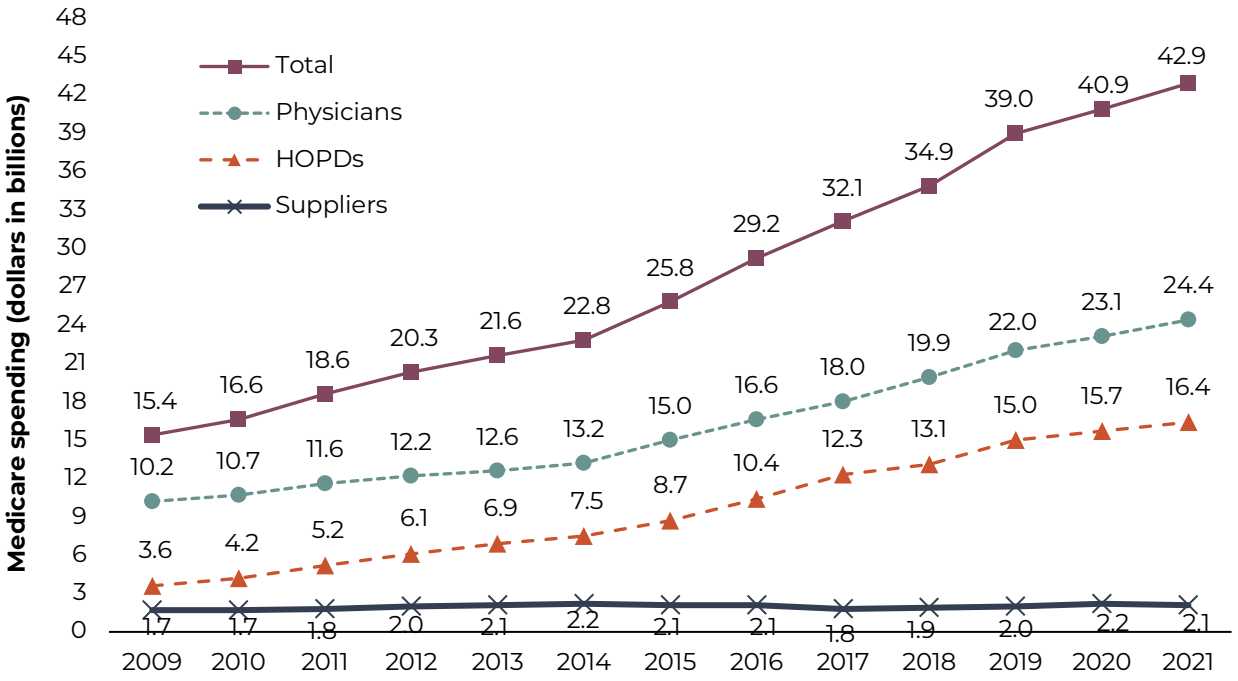
SECTION

10

Prescription drugs

Chart 10-1 Medicare spending for Part B drugs furnished by physicians, hospital outpatient departments, and suppliers, 2009–2021



Note: HOPD (hospital outpatient department). Data include Part B–covered drugs furnished by several provider types, including physicians, suppliers, and HOPDs, and exclude those furnished by critical access hospitals, Maryland hospitals, and dialysis facilities. "Medicare spending" includes program payments and beneficiary cost sharing. Data reflect all Part B drugs whether they were paid based on the average sales price or other methods. Data exclude blood and blood products (other than clotting factor). Components may not sum to totals due to rounding.

Source: MedPAC and Acumen LLC analysis of Medicare claims data.

> The Medicare program and its beneficiaries spent about $43 billion on separately paid Part B drugs in 2021, with physician offices, HOPDs, and suppliers accounting for 57 percent, 38 percent, and 5 percent of spending, respectively.

> Between 2009 and 2021, Part B drug spending grew 8.9 percent per year on average. Growth was more rapid between 2009 and 2019 (9.7 percent per year on average) than between 2019 and 2021 (4.9 percent per year on average). The slower spending growth between 2019 and 2021 reflects the decline in FFS enrollment; controlling for the change in FFS enrollment, spending grew nearly 9 percent per year on average during that period.

> Overall, from 2009 to 2021, Part B drug spending has grown more rapidly for HOPDs than for physicians and suppliers—at average annual rates of about 13 percent, 8 percent, and 2 percent, respectively.

> The data exclude Part B drugs furnished by critical access hospitals and Maryland hospitals, which are not paid under the general Part B drug average sales price payment system. Medicare and beneficiaries spent about $1.2 billion in critical access hospitals and $0.4 billion in Maryland hospitals for Part B drugs in 2021. Also, the data do not reflect Part B drugs paid as part of larger payment bundles (i.e., certain drugs furnished by HOPDs that are packaged into payment for other services and drugs furnished by dialysis facilities that are paid under the broader dialysis payment bundle).

Chart 10-2 Change in Medicare payments and utilization for separately payable Part B drugs, 2009–2021

	2009	2021	Average annual growth 2009–2021
Total payments: Separately payable Part B drugs (in billions)	$11.6*	$40.2*	10.9%*
Total payments: All Part B drugs excluding vaccines (in billions)	$11.4	$39.1	10.8
Number of beneficiaries using a Part B drug (in millions)	2.5	3.6	3.2
Average number of Part B drugs per beneficiary	1.35	1.31	–0.3
Average annual payment per Part B drug per beneficiary	$3,396	$8,241	7.7
Total payments: Part B vaccines (in billions)	$0.2	$1.1	14.2
Number of beneficiaries using a Part B vaccine (in millions)	13.4	14.7	0.7
Average number of Part B vaccines per beneficiary	1.08	1.09	0.1
Average annual payment per Part B vaccine per beneficiary	$15	$67	13.3

Note: This analysis includes Part B drugs paid based on the average sales price as well as the small group of Part B drugs that are paid based on other methods. "Vaccines" refers to three Part B–covered preventive vaccines: influenza, pneumococcal, and hepatitis B. Data include Part B drugs furnished by physicians, hospitals paid under the outpatient prospective payment system, and suppliers and exclude data for critical access hospitals, Maryland hospitals, and dialysis facilities. Yearly figures presented in the table are rounded; the average annual growth rate was calculated using unrounded data.
*For purposes of this analysis, spending on separately payable Part B drugs excludes any drug that was bundled in 2009 or 2021 (i.e., drugs that were packaged under the outpatient prospective payment system in 2009 or 2021 were excluded from both years of the analysis, regardless of the setting where the drug was administered), drugs billed under not-otherwise-classified billing codes, and blood and blood products (other than clotting factor). Without those exclusions, Part B drug spending was $15.4 billion in 2009 and $42.9 billion in 2021, as shown in Chart 10-1.

Source: MedPAC analysis of Medicare claims data for physicians, hospital outpatient departments, and suppliers.

> Total payments by the Medicare program and beneficiaries for separately payable Part B drugs increased 10.9 percent per year, on average, between 2009 and 2021.

> Medicare spending on separately payable Part B drugs excluding Part B–covered preventive vaccines grew at a similar rate (10.8 percent per year) between 2009 and 2021.

> Growth in the average price that Medicare Part B paid per drug was the largest factor contributing to increased spending for separately payable Part B drugs excluding vaccines between 2009 and 2021. During that period, the average annual payment per drug grew 7.7 percent per year on average, which reflects increases in the prices of existing drugs; the launch of new, higher-priced drugs; and shifts in the mix of drugs. Growth in the number of beneficiaries using nonvaccine Part B drugs (about 3.2 percent per year on average) also contributed to increased spending. The number of Part B drugs received per user declined slightly.

> In 2021, Medicare and beneficiaries spent $1.1 billion on three Part B–covered preventive vaccines (influenza, pneumococcal, and hepatitis B) furnished by physicians, hospital outpatient departments, and pharmacy suppliers. Between 2009 and 2021, Part B vaccines spending grew 14 percent per year on average. Almost all of that growth was due to growth in the average payment per vaccine, which climbed at an average rate of 13 percent per year, reflecting higher launch prices for new influenza and pneumococcal vaccines and postlaunch price increases for vaccines.

Chart 10-3 Top 20 Part B drugs, 2021

		2021			Percent change, 2020–2021		
		Total spending (billions)	Number of users	Average spending per user	Total spending	Number of users	Average spending per user
Keytruda	CA	4.0	63,200	$62,900	14%	7%	6%
Eylea	MD	3.4	312,200	11,000	13	9	4
Prolia/Xgeva	CA SE, OS	1.8	627,600	2,800	9	7	2
Opdivo	CA	1.6	25,600	61,500	–1	0	–1
Darzalex	CA	1.5	18,800	81,400	64	32	24
Rituxan*	AR, CA, ID	1.3	64,900	20,100	–17	–3	–14
Lucentis	MD	1.0	115,200	9,100	–6	–5	–1
Orencia	CA SE, RA	1.0	31,700	31,200	–3	5	–8
Avastin*	CA, MD	0.9	191,200	4,600	–14	–6	–9
Neulasta*	CA SE	0.9	85,700	10,100	–29	–4	–26
Tecentriq	CA	0.7	12,700	51,700	5	2	4
Remicade*	AR, ID	0.6	53,900	12,000	–18	0	–18
Soliris	AI	0.6	1,700	382,700	5	0	5
Ocrevus	MS	0.6	12,800	47,600	–2	3	–5
Entyvio	ID	0.5	16,000	32,900	21	14	6
Herceptin*	CA	0.5	18,500	27,600	–25	–4	–22
Gammagard	IMD, NE	0.5	18,800	27,000	30	11	17
Cimzia	AR, ID	0.5	21,500	23,300	–2	9	–10
Alimta	CA	0.5	17,500	27,300	–4	–6	2
Fluzone HD	VA	0.5	7,596,800	62	1	–6	7
Top 10 drugs		17.4					
Top 20 drugs		22.9					
All Part B drugs		42.9					

Note: CA (cancer), MD (macular degeneration and other eye disorders), SE (side effect), OS (osteoporosis), AR (arthritis), ID (inflammatory disorders), AI (autoimmune), MS (multiple sclerosis), IMD (immune deficiency), NE (neuropathy), VA (vaccine), HD (high-dose). "Drug spending" includes Medicare program payments and beneficiary cost sharing. The 20 drugs shown in the chart reflect the Part B drug billing codes with the highest Medicare expenditures in 2021. Data include Part B–covered drugs furnished by several provider types, including physicians, suppliers, and hospital outpatient departments, but exclude those furnished by critical access hospitals, Maryland hospitals, and dialysis facilities. Data exclude blood and blood products (other than clotting factor). Components may not sum to totals due to rounding.
*For originator biologics that have biosimilar competitors, data in the table reflect both the originator biologic and biosimilars.

Source: MedPAC and Acumen LLC analysis of Medicare claims data.

> Part B drugs are billed under roughly 900 billing codes, but spending is concentrated. In 2021, Medicare spending (including cost sharing) on the top 10 products accounted for $17.4 billion, or 41 percent of total Part B drug spending. Spending on the top 20 products accounted for $22.9 billion, or about 53 percent of total Part B drug spending.

> Eighteen of the top 20 Part B products are biologics. One product (Alimta) is a drug, and one (Fluzone HD) is a preventive vaccine.

> The top 20 Part B drugs are concentrated in certain therapeutic areas. Eight of the top 20 drugs treat cancer and three treat cancer side effects. The top 20 also includes 3 products for macular degeneration and 5 products for rheumatoid arthritis or other inflammatory disorders.

(Chart continued next page)

Chart 10-3 Top 20 Part B drugs, 2021 (continued)

> Among the top 20 highest-expenditure Part B drugs, average total spending per user varies. Of seven products used to treat cancer (excluding Avastin, for which costs vary substantially depending on whether it is used for cancer or macular degeneration), average spending per user ranged from $20,000 to $81,000, with four products averaging $50,000 or more per user. Average spending per user ranged from $12,000 to $33,000 for five drugs used to treat rheumatoid arthritis and other inflammatory conditions, and from $9,000 to $11,000 for two drugs used to treat macular degeneration (excluding Avastin). Soliris, a product used to treat rare autoimmune conditions, had the highest average cost per user among the top 20, $383,000.

> Between 2020 and 2021, total spending increased for 9 of the top 20 Part B drugs and decreased for 11 drugs. Darzalex experienced the largest total spending growth (64 percent), driven by a 32 percent increase in the number of users and a 24 percent increase in the average spending per user. Gammagard also experienced large total spending growth (30 percent). In 2021, total spending also increased more than 10 percent for Keytruda, Eylea, and Entyvio. Among the products that experienced spending decreases in 2021, the most substantial decreases occurred among the five products with biosimilar competition (Avastin, Herceptin, Neulasta, Remicade, and Rituxan), ranging from 14 percent to 29 percent.

Chart 10-4 Growth in manufacturer prices for the 20 highest-expenditure Part B drugs, 2015–2023

	Total Medicare payments in 2021 (in billions)	Average annual percentage change in average sales price 2015–2022	Percentage change in average sales price 2022–2023
Keytruda	4.0	2.3%[d]	3.1%
Eylea	3.4	–1.0	–1.9
Prolia/Xgeva	1.8	5.4	8.8
Opdivo	1.6	2.4[d]	2.6
Darzalex	1.5	4.0[e]	3.0
Rituxan[a]	1.3	2.4	–4.5
Lucentis[a]	1.0	–3.6	–22.8
Orencia	1.0	4.3	–2.3
Avastin[a]	0.9	0.0	4.3
Neulasta[a]	0.9	–6.5	–25.7
Tecentriq	0.7	1.2[f]	1.5
Remicade[a]	0.6	–9.2	–7.5
Soliris	0.6	1.2	–0.8
Ocrevus	0.6	0.8[f]	1.3
Entyvio	0.5	3.8[d]	1.9
Herceptin[a]	0.5	0.3	–4.2
Gammagard	0.5	2.5	–2.4
Cimzia	0.5	0.2	–19.3
Alimta[b]	0.5	3.3	–63.6
Fluzone HD[c]	0.5	10.1	7.2
Consumer Price Index for Urban Consumers		2.7	6.4

Note: Growth rates are calculated for: average sales price (ASP) from first quarter to first quarter of each year and for the Consumer Price Index for Urban Consumers (CPI–U) from January to January of each year. If a product launched after 2015, the table displays average annual ASP growth between the earliest year that a first-quarter payment rate was available for the product and 2022. ASP at the billing code level is calculated using the publicly available Part B drug payment rate data on CMS's website. "Medicare payments" includes Medicare program payments and beneficiary cost sharing for these drugs furnished by physicians, suppliers, and hospital outpatient departments, but excludes those furnished by critical access hospitals, Maryland hospitals, and dialysis facilities.
[a]Indicates the product is an originator biologic that has experienced biosimilar entry. ASP trends are for the originator product only.
[b]Indicates the drug has experienced generic entry. ASP trend is for the billing code that originally contained the brand product and now contains the brand and its generic equivalents.
[c]For Fluzone HD, a preventive vaccine paid 95 percent of the average wholesale price, the table displays the percent change in the actual payment rate rather than ASP.
[d]ASP growth for period from 2016 to 2022.
[e]ASP growth for period from 2017 to 2022.
[f]ASP growth for period from 2018 to 2022.

Source: MedPAC analysis of CMS ASP payment rate files publicly available on the CMS website and CPI–U data from the Bureau of Labor Statistics and MedPAC and Acumen LLC analysis of Medicare claims data.

(Chart continued next page)

Chart 10-4 Growth in manufacturer prices for the 20 highest-expenditure Part B drugs, 2015–2023 (continued)

> Medicare pays for most Part B drugs at a rate of 106 percent of the average sales price (ASP + 6 percent). ASP is the average price realized by the manufacturer for sales to most U.S. purchasers, net of rebates, discounts, and price concessions, with certain exceptions. For brand-name products with no generic competitors, Medicare Part B pays each product an ASP-based rate under the product's own billing code. This policy means that Medicare pays whatever price the manufacturer establishes. For brand drugs with generic competitors, Medicare Part B assigns both the brand product and its generic equivalents to the same billing code and pays 106 percent of a volume-weighted ASP. This policy creates incentives for providers to select the lower-cost product within a billing code, which in turn lowers the volume-weighted ASP in future quarters, leading to substantial price reductions in payment rates for brand products after generic entry.

> From 2015 to 2022, 15 out of 20 of the top Part B drugs experienced net price increases, with 6 of these products' prices increasing faster than the CPI–U on net over the 7-year period (or between launch and 2022 if the product launched after 2015): Alimta, Darzalex, Entyvio, Fluzone HD, Orencia, and Prolia/Xgeva. (Fluzone HD, which is a preventive vaccine, is paid 95 percent of the average wholesale price instead of 106 percent of ASP.)

> In the most recent year, more products in the top 20 experienced a price decrease than a price increase. Prices decreased for 11 products and increased for 9 products between the first quarters of 2022 and 2023. Between the first quarters of 2022 and 2023, a year with high inflation (6.4 percent growth in CPI–U), two of the nine products with price increases experienced increases greater than inflation (Prolia/Xgeva, 8.8 percent, and Fluzone HD, 7.2 percent).

> The largest price decrease in 2023 occurred for Alimta, a drug that faced generic entry in the first half of 2022. Alimta and its generic equivalents are paid under a single billing code based on the volume-weighted average sales price for the products, and the payment rate declined 64 percent between January 2022 and 2023.

> Some of the price declines in 2023 among the top 20 products occurred among biologics facing biosimilar competition. Avastin, Herceptin, Neulasta, Lucentis, Remicade, and Rituxan all have biosimilar competitors. Prices for these originator biologics (except for Avastin) declined by 4 percent to 26 percent between 2022 and 2023. Originator Avastin's price increased 4 percent between January 2022 and 2023, despite facing biosimilar competition.

Chart 10-5 Trends in Medicare Part B payment rates for originator biologics and their biosimilar products

	First biosimilar entry	Percent change in originator biologic's ASP		Biosimilars' payment rate as a percent of originator biologic's payment rate (2023 Q1)	Biosimilar market share (2022 Q3)
		In 10 years before biosimilar entry	Since biosimilar entry (through 2023 Q1)		
Neupogen and biosimilars	2015 Q3	71%	–2%	24%–41%	83%
Remicade and biosimilars	2016 Q4	54%	–58%	71%–130%	26%
Neulasta and biosimilars	2018 Q3	117%	–66%	67%–108%	43%
Procrit/Epogen and biosimilars	2018 Q4	35%	–33%	98%	52%
Avastin and biosimilars	2019 Q3	42%	–13%	45%–48%	77%
Herceptin and biosimilars	2019 Q3	69%	–23%	40%–71%	74%
Rituxan and biosimilars	2019 Q4	68%	–14%	40%–61%	59%
Lucentis and biosimilars	2022 Q3	-31%	-14%	99%	N/A

Note: ASP (average sales price), Q1 (first quarter), Q3 (third quarter), Q4 (fourth quarter). An originator biologic is a drug product derived from a living organism. A biosimilar product is a follow-on product that is approved by the Food and Drug Administration (FDA) based on the product being highly similar to the originator biologic. The biosimilars included in the analysis are Zarxio, Nivestym, and Granix for originator Neupogen; Inflectra, Renflexis, and Avsola for originator Remicade; Fulphila, Udenyca, Nyvepria, and Ziextenzo for originator Neulasta; Retacrit for originator Procrit/Epogen; Mvasi and Zirabev for originator Avastin; Ontruzant, Herzuma, Ogivri, Trazimera, and Kanjinti for originator Herceptin; Truxima, Ruxience, and Riabni for originator Rituxan, and and Byooviz for originator Lucentis. Although Granix is not a biosimilar in the U.S. (because it was approved under the standard FDA approval process for new biologics), we include it here because it was approved as a biosimilar to Neupogen in Europe and it functions as a competitor to Neupogen in the U.S. market. "First biosimilar entry date" reflects the earliest market date for a product approved by the FDA as a biosimilar to the originator biologic.

Source: MedPAC analysis of ASP payment rate files publicly available on the CMS website and product market date information from CMS's database on drug products in the Medicaid Drug Rebate Program and Acumen LLC analysis of Medicare claims data.

> Under Part B, Medicare pays for an originator biologic at 106 percent of its own ASP. For biosimilars, Medicare pays 100 percent of the biosimilar's ASP plus 6 percent or 8 percent of the originator product's ASP. Per the Inflation Reduction Act of 2022, for five years, existing biosimilars beginning October 2022 and new biosimilars receive an 8 percent add-on, as long as the biosimilar's ASP does not exceed the originator's ASP.

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Chart 10-5 Trends in Medicare Part B payment rates for originator biologics and their biosimilar products (continued)

> Biosimilar entry has generated savings for Medicare. Between 2020 and 2021, Medicare spending on Part B originator biologics and their biosimilars declined by about 20 percent from $5.5 billion to $4.4. billion (data not shown). Pricing patterns and biosimilar uptake vary across products.

> For some products, biosimilars are priced substantially below originators and biosimilar uptake has driven savings. For example, Neupogen, the originator biologic that has faced biosimilar competition for the longest period (since the third quarter of 2015), has not significantly reduced its price and has lost most of its market share to biosimilars. As of the first quarter of 2023, biosimilars' payment rates were much lower than the originator's payment rate (roughly 60 percent to 75 percent below the originator's payment rate). Biosimilars accounted for about 83 percent of market share as of the third quarter of 2022.

> For other products, reference biologics have responded to biosimilar entry by lowering their prices, and savings have come from both the originator biologic and biosimilars. For example, the price of the originators Procrit/Epogen has fallen 33 percent since biosimilar entry in the fourth quarter of 2018, and the price of the originator Lucentis has fallen 14 percent since biosimilar entry in the third quarter of 2022. For both of these products, Medicare's payment rate for the biosimilars is slightly lower (1 percent or 2 percent) than for the originators, as of the first quarter of 2023.

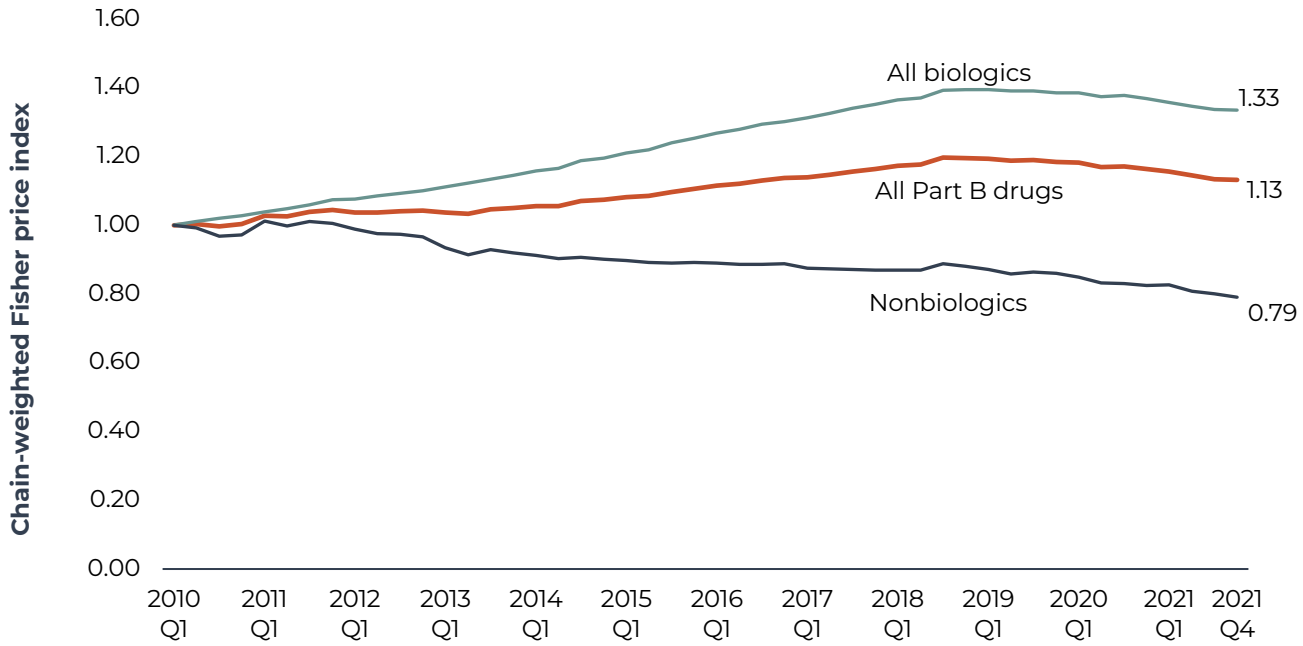
> In a few cases, originator biologics have reduced their prices by more than 50 percent in response to biosimilar entry. Originator Remicade's payment rate has declined 58 percent and originator Neulasta's payment rate has declined 66 percent since biosimilar entry. Nonetheless, as of the first quarter of 2023, both products had some biosimilar competitors on the market that were priced substantially lower (roughly 30 percent below the originator's payment rate). Originators Remicade and Neulasta continue to retain the majority of market share, accounting for 74 percent and 57 percent of utilization in the third quarter of 2022, respectively.

> In 2019, three originator biologics used to treat cancer (Avastin, Herceptin, Rituxan) faced biosimilar entry, representing the first availability of biosimilar anticancer agents. Biosimilars for these three products have rapidly gained market share, with biosimilars accounting for between 59 percent and 77 percent of utilization among these products as of the third quarter of 2022.

> Lucentis is the most recent Part B biologic to face biosimilar competition, with a biosimilar entering in the third quarter of 2022. In the two quarters since biosimilar entry, Lucentis's payment rate has declined 14 percent, and Lucentis and its biosimilar have similar payment rates as of the first quarter of 2023.

> Although biosimilar competition has resulted in reduced prices for originator biologics relative to the products' prices at the time of biosimilar entry, nearly all of these originator biologics experienced substantial price increases prior to biosimilar entry. With the exception of Lucentis, the originator biologics' cumulative growth in payment rates over the 10 years prior to biosimilar entry ranged from 35 percent to 117 percent. In contrast, Lucentis's payment rate declined 31 percent in the 10 years before biosimilar entry.

Chart 10-6 Price indexes for Medicare Part B drugs, 2010–2021



Note: Q1 (first quarter), Q4 (fourth quarter). The Part B price indexes are Fisher price indexes and reflect growth in the average sales price of Part B–covered drugs over time, measured for individual drugs at the level of the Healthcare Common Procedure Coding System billing code. The price index is different from the change in the aggregate average price Medicare pays for drugs (Chart 10-2), which reflects changes in the prices of existing products, rising launch prices of new products, and shifts in the mix of drugs.

Source: Acumen LLC analysis for MedPAC.

> The Part B price indexes reflect growth in the average sales price (ASP) at the individual product level, which is a measure of average postlaunch price growth for Part B drugs. This measure is different from the change in the aggregate average price Medicare Part B pays for drugs (Chart 10-2), which reflects a broader set of dynamics (including changes in the price of existing products, rising launch prices of new products compared with older products, and shifts in the mix of drugs).

> Measured by the change in the ASP of individual Part B–covered drugs, the prices of Part B–covered drugs rose by an average of 13 percent cumulatively between 2010 and 2021 (index of 1.13). Since the third quarter of 2018 through the end of 2021, the overall price index for Part B drugs has declined from 1.20 to 1.13, driven by a decline in the biologics' price index, coupled with the continued decline in the nonbiologics' price index.

> The price index for biologics increased cumulatively by 33 percent (index of 1.33) between 2010 and 2021, reaching a high of 1.39 in the first quarter of 2019 and declining to 1.33 by the fourth quarter of 2021. Pricing trends differ for biologics that face biosimilar competition and biologics that do not. Between the first quarter of 2019 and the fourth quarter of 2021, the price index declined for biologics with recent biosimilar entry by roughly one third and increased for biologics without biosimilar competition by about 3 percent.

> The price index for nonbiologics declined 21 percent (index of 0.79) between 2010 and 2021, which in part reflects patent expiration and generic entry for some of these products. The design of the ASP payment system spurs price competition among generics and their associated brand products by paying them the same rate under a combined billing code.

Chart 10-7 Part D enrollment by plan type, 2014–2022

	2014	2021	2022	Average annual growth rate 2014-2022
Total Medicare enrollment, in millions	56.9	66.9	68.1	2.3%
Part D enrollment, in millions				
Part D plans	40.0	51.6	53.1	3.6
Non-Medicare employer plans under the RDS*	2.8	1.2	1.1	–11.0
Total Part D	42.8	52.8	54.2	3.0
Total Part D share of Medicare enrollment	*75%*	*79%*	*79%*	
LIS enrollment				
PDP	9.2	6.7	6.2	–4.8
MA–PD	3.6	7.6	8.5	11.5
Total LIS	12.8	14.3	14.8	1.8
Share of LIS enrollees in MA–PD	*28%*	*53%*	*58%*	
Share of Part D plan enrollees with LIS	*32%*	*28%*	*28%*	
EGWPs (PDPs and MA–PDs), in millions	7.0	7.8	7.9	1.5
EGWP share of total Part D enrollment	*16%*	*15%*	*15%*	
Non-EGWP Part D plans, in millions				
PDP	20.1	20.9	20.2	0.1
MA–PD	13.0	22.9	25.0	8.5
Share of non-EGWP plan enrollees in MA–PD	*39%*	*52%*	*55%*	

Note: RDS (retiree drug subsidy), LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), EGWP (employer group waiver plan). A beneficiary was classified as "LIS" if that individual received Part D's LIS at some point during the year. If a beneficiary was enrolled in both a PDP and an MA–PD during the year, that individual was classified into the type of plan with the greater number of months of enrollment. Components may not sum to totals due to rounding. Average annual growth rate is calculated on unrounded numbers. Figures include all beneficiaries with at least one month of enrollment.
*Excludes federal government and military retirees covered by either the Federal Employees Health Benefit Program or the TRICARE for Life program.

Source: MedPAC analysis of common Medicare environment file from CMS.

> In 2022, 79 percent of Medicare beneficiaries were enrolled in Part D plans for at least one month during the year or had prescription drug coverage through employer-sponsored plans that receive Medicare's RDS. That share is up from 75 percent in 2014.

> Between 2014 and 2022, the number of enrollees receiving the LIS grew modestly (1.8 percent per year, on average) compared with the number of non-LIS enrollees (about 4.4 percent per year, on average, data not shown). Faster enrollment growth among non-LIS enrollees has resulted in a decline in the share of Part D enrollees who receive the LIS. In 2022, 28 percent of Part D enrollees received the LIS, a decrease from 32 percent in 2014. Over 58 percent of LIS beneficiaries were in MA–PDs.

> Employer and union health plans continue to be important sources of drug coverage for Medicare beneficiaries. In 2022, 7.9 million Medicare beneficiaries (15 percent of Part D plan enrollees) were in plans (including PDPs and MA–PDs) set up by employers or unions for their retirees. Under these EGWPs, Medicare is the primary payer for basic drug benefits, and typically the employer offers wraparound coverage. Separately, 1.1 million Medicare beneficiaries were in plans offered by employers that receive Medicare's RDS. (If an employer remains the primary payer of creditable drug coverage for its retirees, Medicare provides the employer with a tax-free subsidy for 28 percent of each eligible individual's drug costs that fall within a specified range of spending.)

> In 2022, among non-EGWP plans, 25 million (55 percent) were in MA–PDs and 20.2 million (45 percent) were in stand-alone PDPs. Over the 2014 to 2022 period, enrollment in PDPs remained flat while enrollment in MA–PDs rose by an annual average of 8.5 percent.

Chart 10-8 Characteristics of Part D enrollees, 2022

	All Medicare	Part D	Plan type		Subsidy status	
			PDP	MA–PD	LIS	Non-LIS
Beneficiaries* (in millions)	68.1	53.1	24.8	28.2	14.8	38.3
Percent of all Medicare	100%	78%	36%	41%	22%	56%
Gender						
Male	46%	44%	43%	44%	41%	44%
Female	54	56	57	56	59	56
Race/ethnicity						
White, non-Hispanic	73	73	80	66	52	81
Black, non-Hispanic	11	11	7	14	20	7
Hispanic	9	9	5	13	17	6
Asian	4	4	3	4	7	3
Other	4	3	4	3	4	3
Age (years)**						
<65	14	14	13	15	36	6
65–69	27	25	24	26	22	27
70–74	23	23	23	23	15	26
75–79	16	17	17	17	11	19
80+	20	21	22	19	17	22

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income subsidy). Components may not sum to totals due to rounding.
*Figures for "All Medicare" and "Part D" include all beneficiaries with at least one month of enrollment in the respective program. A beneficiary was classified as "LIS" if that individual received Part D's LIS at some point during the year. For individuals who switched plan types during the year, classification into plan types was based on the greater number of months of enrollment.
**Age as of July 2022.

Source: MedPAC analysis of the common Medicare environment file from CMS.

> In 2022, 53.1 million Medicare beneficiaries (78 percent) were enrolled in Part D plans at some point in the year. Less than half (24.8 million) were enrolled in stand-alone PDPs, while the rest were enrolled in MA–PDs (28.2 million). Just under 15 million enrollees received Part D's LIS.

> Demographic characteristics of Part D enrollees are generally similar to the overall Medicare population, with the exception of gender (Part D enrollees are more likely to be female). MA–PD enrollees are more likely to be Hispanic or Black compared with PDP enrollees; LIS enrollees are more likely to be female, minority, and beneficiaries under age 65 (eligible for Medicare due to disability) compared with non-LIS enrollees.

Chart 10-9 Changes in parameters of the Part D defined standard benefit over time, 2014–2023

	2014	2022	2023	Average annual change 2014–2023
Deductible	$310	$480	$505	5.6%
Initial coverage limit	2,850	4,430	4,660	5.6
Annual out-of-pocket threshold	4,550	7,050	7,400	5.6
Total covered drug spending at annual out-of-pocket threshold				
Enrollees eligible for manufacturers' coverage-gap discount	6,691	10,690	11,206	5.9
Other enrollees	6,455	10,013	10,516	5.6
Cost sharing above the annual out-of-pocket threshold is the greater of 5% coinsurance or these amounts:				
Copay for generic/preferred multisource drugs	2.55	3.95	4.15	5.6
Copay for other prescription drugs	6.35	9.85	10.35	5.6

Note: Under Part D's defined standard benefit, the enrollee pays the deductible and then 25 percent of covered drug spending (75 percent is paid by the plan) until total covered drug spending reaches the initial coverage limit. The amounts of total covered drug spending at the annual out-of-pocket (OOP) threshold are for individuals who have no source of supplemental coverage and an average mix of brand and generic spending. Cost sharing paid by most sources of supplemental coverage does not count toward this threshold. Above the OOP limit, the enrollee pays 5 percent coinsurance or the respective copay shown above, whichever is greater.

Source: CMS Office of the Actuary.

> In 2023, Part D's defined standard benefit has a $505 deductible, 25 percent coinsurance on covered drugs until the enrollee reaches $4,660 in total covered drug spending, and then a coverage gap until OOP spending reaches the annual threshold. (The total dollar amount of drug spending at which a beneficiary reaches the OOP threshold varies from person to person, depending on the mix of brand-name and generic prescriptions filled. CMS estimates that in 2023, a person who does not receive Part D's low-income subsidy (LIS) and has no supplemental coverage would, on average, reach the threshold at $11,206 in total drug spending.) Most enrollees pay about 25 percent cost sharing for brand or generic prescriptions filled in the coverage gap. Beneficiaries who do not receive the LIS are eligible for a 70 percent manufacturers' discount on brand prescriptions in the gap phase. Enrollees with drug spending that exceeds the annual threshold pay the greater of $4.15 to $10.35 or 5 percent coinsurance per prescription. CMS updates most parameters of this defined standard benefit structure each year by the annual change in average total drug expenses of Medicare beneficiaries enrolled in Part D.

> Within certain limits, sponsors may offer Part D plans that have the same actuarial value as the defined standard benefit but a different benefit structure. For example, a plan may use tiered copayments rather than 25 percent coinsurance or have no deductible but use cost-sharing requirements that are equivalent to a rate higher than 25 percent (see Chart 10-15). Defined standard benefit plans and plans that are actuarially equivalent to the defined standard benefit are both known as "basic benefits." Once a sponsoring organization offers one plan with basic benefits within a prescription drug plan region, it may also offer up to two plans with enhanced benefits—basic and supplemental coverage combined.

> Several changes to Part D's benefit design are underway as a result of enactment of the Inflation Reduction Act of 2022. (See the Commission's March 2023 report for more details.) In 2023, enrollees pay reduced cost sharing for insulin and no cost sharing for recommended vaccines. In 2024, enrollees will pay no cost sharing after reaching the OOP threshold. In 2025, Medicare will implement a redesign of the Part D benefit that will cap enrollees' OOP spending at $2,000, among other measures. The OOP cap will be updated annually in the same manner as other Part D parameters.

Chart 10-10 Characteristics of stand-alone Medicare PDPs, 2022–2023

	2022				2023			
	Plans		Enrollees as of February 2022		Plans		Enrollees as of February 2023	
	Number	Percent	Number (in millions)	Percent	Number	Percent	Number (in millions)	Percent
Total	766	100%	19.0	100%	804	100%	18.5	100%
Type of benefit								
Defined standard	0	0	0.0	0	0	0	0.0	0
Actuarially equivalent	302	39	8.7	46	305	38	7.9	43
Enhanced	464	61	10.3	54	499	62	10.6	57
Type of deductible								
Zero	136	18	2.7	14	133	17	2.6	14
Reduced	90	12	1.2	6	110	14	2.0	11
Defined standard*	540	70	15.1	79	561	70	13.9	75
Some formulary tiers not subject to a deductible	405	53	11.9	63	423	53	9.3	50

Note: PDP (prescription drug plan). The PDPs and enrollment described here exclude employer-only plans and plans offered in U.S. territories. "Actuarially equivalent" includes both actuarially equivalent standard and basic alternative benefits. "Enhanced" refers to plans with basic plus supplemental coverage. Components may not sum to totals due to rounding.
*The defined standard benefit's deductible was $480 in 2022 and is $505 in 2023.

Source: MedPAC analysis of CMS landscape, premium, and enrollment data.

> Plan sponsors are offering 804 stand-alone PDPs in 2023 compared with 766 in 2022—an increase of 5 percent. Total enrollment in PDPs declined by 2.7 percent to 18.5 million beneficiaries in 2023 from 19.0 million in 2022, as enrollees shifted to MA–PDs (see Chart 10-7).

> For 2023, 62 percent of PDP offerings include enhanced benefits (basic plus supplemental coverage); this share has remained steady since 2019 (2019 data not shown). Enhanced plans have maintained their higher share of enrollment, up to 57 percent in 2023, since reaching 50 percent in 2021 (latter data not shown).

> In 2023, 70 percent of PDPs use the same $505 deductible as in Part D's defined standard benefit, the same as in 2022. Only 25 percent of PDP enrollees are in plans with either no or a reduced deductible. Also in 2023, 53 percent of all PDPs designate certain formulary tiers that are not subject to the deductible. If, for example, a PDP used such a designation for preferred generic drugs, an enrollee would pay just the plan's cost sharing for that tier rather than the full cost of the prescription up to the amount of the deductible. In 2023, just 50 percent of PDP enrollees were in such plans, down from 63 percent in 2022.

Chart 10-11 Characteristics of general MA–PDs, 2022–2023

	2022				2023			
	Plans		Enrollees as of February 2022		Plans		Enrollees as of February 2023	
	Number	Percent	Number (in millions)	Percent	Number	Percent	Number (in millions)	Percent
Total	3,365	100%	18.1	100%	3,540	100%	18.8	100%
Type of organization								
Local HMO	2,052	61	11.7	64	2,086	59	11.7	62
Local PPO	1,261	37	6.0	33	1,404	40	6.8	36
PFFS	19	1	0.0	0	17	0	0.0	0
Regional PPO	33	1	0.4	2	33	1	0.3	2
Type of benefit								
Defined standard	25	1	0.1	<0.5	14	<0.5	0.0	<0.5
Actuarially equivalent	51	2	0.1	1	57	2	0.1	1
Enhanced	3,289	98	17.9	99	3,469	98	18.7	99
Type of deductible								
Zero	1,900	56	11.3	63	2,337	66	14.3	76
Reduced	1,229	37	6.2	34	1,045	30	4.2	22
Defined standard*	236	7	0.6	3	158	4	0.3	2
Some formulary tiers not subject to a deductible	1,415	42	6.7	37	1,154	33	4.4	23

Note: MA–PD (Medicare Advantage–Prescription Drug [plan]), HMO (health maintenance organization), PPO (preferred provider organization), PFFS (private fee-for-service). The MA–PDs and enrollment described here exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, and Part B–only plans. Components may not sum to totals due to rounding. "Actuarially equivalent" includes both actuarially equivalent standard and basic alternative benefits. "Enhanced" refers to plans with basic plus supplemental coverage.
*The defined standard benefit's deductible was $480 in 2022 and is $505 in 2023.

Source: MedPAC analysis of CMS landscape, premium, and enrollment data.

> Sponsors are offering 3,540 MA–PDs in 2023 compared with 3,365 in 2022 (5 percent more). Enrollment in MA–PDs grew 4.1 percent from 18.1 million in 2022 to 18.8 million in 2023—a continued deceleration from more than 10 percent growth in 2020 and 2021 (data not shown).

> Between 2022 and 2023, the number of drug plans offered by HMOs grew modestly from 2,052 to 2,086; HMO drug plans remain the dominant type of MA–PD, making up 59 percent of all offerings. But local PPOs are growing in popularity. Over the same period, the number of drug plans offered by local PPOs increased 11 percent from 1,261 plans to 1,404 plans, and their enrollees grew from 6.0 million to 6.8 million.

> In 2023, 98 percent of MA–PDs have enhanced benefits compared with 62 percent of PDPs (see Chart 10-10). In 2023, those MA–PDs enrolled 99 percent of all MA–PD beneficiaries.

> Sixty-six percent of MA–PDs have no deductible in 2023—an increase of 10 percentage points from 2022—and those plans attracted more than three-fourths of all MA–PD enrollees. In addition, 23 percent of enrollees are in plans that designate certain cost-sharing tiers of their formularies that are not subject to a deductible.

Chart 10-12 Characteristics of SNPs, 2022–2023

	2022				2023			
	Plans		Enrollees as of February 2022		Plans		Enrollees as of February 2023	
	Number	Percent	Number (in millions)	Percent	Number	Percent	Number (in millions)	Percent
Total	1,130	100%	4.3	100%	1,254	100%	5.3	100%
Type of SNP								
Chronic condition	267	24	0.4	9	300	24	0.4	8
Dual eligible	679	60	3.8	89	765	61	4.7	90
Institutionalized	184	16	0.1	2	189	15	0.1	2
Type of benefit								
Defined standard	347	31	2.0	46	644	51	3.6	68
Actuarially equivalent	68	6	0.5	11	25	2	0.1	1
Enhanced	715	63	1.8	43	585	47	1.6	31
Type of deductible								
Zero	241	21	0.2	5	296	24	0.4	7
Reduced	140	12	0.4	9	57	5	0.2	4
Defined standard*	749	66	3.7	86	901	72	4.7	89
Some formulary tiers not subject to a deductible	377	33	1.4	33	130	10	0.4	8

Note: SNP (special needs plan), HMO (health maintenance organization), PPO (preferred provider organization), PFFS (private fee-for-service). The SNPs and enrollment described here exclude plans offered in U.S. territories. Components may not sum to totals due to rounding. "Actuarially equivalent" includes both actuarially equivalent standard and basic alternative benefits. "Enhanced" refers to plans with basic plus supplemental coverage. *The defined standard benefit's deductible was $480 in 2022 and is $505 in 2023.

Source: MedPAC analysis of CMS landscape, premium, and enrollment data.

> The number of SNPs (MA–PDs designed for certain groups of beneficiaries) has grown rapidly; in 2023, there are 11 percent more than in 2022. Enrollment in SNPs grew 22.5 percent from 4.3 million in 2022 to 5.3 million in 2023—continuing the trend of double-digit growth that has occurred since 2017.

> SNPs for individuals dually eligible for Medicare and Medicaid (D–SNPs) are the most popular type. In 2023, 61 percent of SNPs were D–SNPs, and they enrolled 90 percent of all SNP enrollees. Other types of SNPs include those for individuals who have certain chronic conditions and those for institutionalized beneficiaries.

> Compared with PDPs and MA–PDs, SNPs are more likely to offer a defined standard benefit, with more than half of SNPs now offering such coverage. In 2023, these plans enrolled more than two-thirds of SNP beneficiaries. There was a sharp decline in the number of SNPs providing enhanced coverage in 2023, and enrollment in such plans fell to 31 percent of all SNP enrollees.

> Dually eligible beneficiaries automatically receive Part D's low-income subsidy, which means that most recipients pay nominal copayments while the subsidy pays the remainder of their plan's cost sharing. Because nominal copayments limit the effectiveness of a formulary with tiered cost sharing, sponsors of D–SNPs more frequently use Part D's defined standard benefit design. For the same reason, D–SNPs are also less likely to have some formulary tiers not subject to a deductible.

Chart 10-13 Change in average Part D premiums, 2014–2023

	2014	2022	2023	Cumulative change in weighted average premium, 2014–2023
All plans	$29	$26	$26	–$3
Basic plans	29	34	35	6
Enhanced plans				
Basic benefits	24	15	13	–11
Supplemental benefits	6	8	9	4
Total premium	30	23	22	–7
All basic coverage	26	21	19	–7
PDPs	38	40	41	3
Basic plans	30	35	36	7
Enhanced plans				
Basic benefits	39	23	19	–20
Supplemental benefits	10	21	25	16
Total premium	49	44	44	–5
All basic coverage	34	28	26	–7
MA–PDs, including SNPs	16	15	15	–1
Basic plans	25	33	32	7
Enhanced plans				
Basic benefits	11	11	10	–1
Supplemental benefits	2	1	1	–1
Total premium	13	12	11	–2
All basic coverage	14	14	14	0
Average MA–PD buy-down of basic premium	13	22	23	10
Average MA–PD buy-down of supplemental benefits	13	26	31	18
Base beneficiary premium	32.42	33.37	32.74	0.32

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), SNP (special needs plan). All calculations exclude employer-only groups and plans offered in U.S. territories. In addition, MA–PDs exclude Part B–only plans, demonstrations, and 1876 cost plans. The MA–PD data reflect the portion of Medicare Advantage plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage, as well as Part C rebate dollars that were used to offset Part D premium costs. The fact that average premiums for enhanced MA–PDs are lower than for basic MA–PDs could reflect several factors such as changes in enrollment among plan sponsors and counties of operation and differences in the average health status of plan enrollees. Cumulative changes were calculated from unrounded data. Components may not sum to totals due to rounding.

Source: MedPAC analysis of CMS landscape, plan report, enrollment data, and bid data.

> Part D enrollees can select between plans with basic or enhanced benefits (the latter combine basic and supplemental coverage). Medicare aims to subsidize 74.5 percent of the average cost of basic benefits; enrollees pay premiums for the remaining 25.5 percent and all of the cost of any supplemental benefits. (For more about how plan premiums are determined, see Part D *Payment Basics* at https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_PartD_FINAL_SEC.pdf.)

(Chart continued next page)

Chart 10-13 Change in average Part D premiums, 2014–2023 (continued)

> The overall average premium paid by enrollees for any type of Part D coverage declined only slightly in 2023 from 2022, rounding to $26 per month for the third straight year (2021 data not shown). Over the period from 2014 to 2023, year-to-year changes in average premiums have varied by type of benefit (premiums for basic plans have grown while premiums for enhanced plans have declined) and type of plan (PDP premium components have changed at slower rates than those for MA–PDs). The base beneficiary premium has fluctuated over the years but is now just slightly higher than it was in 2014.

> Across all basic plans and the basic portion of enhanced plans, the average premium for basic benefits fell from $26 in 2014 to $19 per month in 2023, a cumulative decline of 27 percent. This decline occurred despite very rapid growth in spending for Part D's catastrophic phase of the benefit (data not shown). In the catastrophic phase, Medicare subsidizes 80 percent of enrollees' drug spending. (For more information about Medicare's Part D spending, see Chapter 12 of the Commission's March 2023 report to the Congress at https://www.medpac.gov/wp-content/uploads/2023/03/Ch12_Mar23_MedPAC_Report_To_Congress_SEC.pdf.)

> Between 2014 and 2023, the average premium for basic coverage in a PDP increased by nearly $7 but fluctuated between $28 in 2015 (data not shown) and $36 in 2023. Among enhanced plans offered by PDPs, the average enrollee premium was $44 in 2023. Over the past 10 years, the average premium for these plans decreased by $5. Of the $44 average premium in 2023 among enhanced PDPs, $19 was for basic benefits and $25 was for supplemental benefits. The portion of enhanced premiums attributable to supplemental benefits has grown, while the portion for basic benefits has declined.

> From 2014 to 2023, the average premium for basic coverage in an MA–PD also increased by $7, ranging from $21 in 2015 (data not shown) to $33 per month in 2022. The average premium paid by beneficiaries enrolled in MA–PDs offering enhanced coverage is down to $11 in 2023, a decrease of $2 since 2014. MA–PD sponsors typically use a portion of Medicare's Part C (Medicare Advantage) payments to "buy down" the premiums that plan enrollees would otherwise have to pay for Part D basic premiums and supplemental benefits. Because of those Part C payment "rebates," in 2023, MA–PD enrollees avoided having to pay $23 per month in basic premiums and an additional $31 per month for supplemental coverage, on average.

Chart 10-14 Part D benchmarks for LIS premiums and number of qualifying PDPs, by region

Region	State(s)	2014		2023		Cumulative change, 2014–2023	
		Benchmark amount	Number of PDPs	Benchmark amount	Number of PDPs	Benchmark amount	Number of PDPs
1	ME, NH	$28	7	$31	5	$3	–2
2	CT, MA, RI, VT	28	8	36	6	8	–2
3	NY	37	8	39	3	2	–5
4	NJ	37	12	35	6	–2	–6
5	DC, DE, MD	32	13	39	5	7	–8
6	PA, WV	36	13	41	7	6	–6
7	VA	29	13	35	6	5	–7
8	NC	28	10	38	5	10	–5
9	SC	34	8	38	5	4	–3
10	GA	29	9	37	6	8	–3
11	FL	22	5	36	4	14	–1
12	AL, TN	30	11	35	7	5	–4
13	MI	32	13	33	7	0	–6
14	OH	29	12	35	4	6	–8
15	IN, KY	35	15	28	5	–7	–10
16	WI	37	12	43	7	6	–5
17	IL	29	14	27	7	–1	–7
18	MO	31	8	36	5	5	–3
19	AR	30	12	32	5	2	–7
20	MS	31	13	32	6	1	–7
21	LA	32	14	38	6	7	–8
22	TX	28	11	25	5	–3	–6
23	OK	30	12	33	6	3	–6
24	KS	34	13	33	5	–1	–8
25	IA, MN, MT, ND, NE, SD, WY	32	10	40	6	8	–4
26	NM	20	7	36	7	16	0
27	CO	27	5	42	5	15	0
28	AZ	27	11	43	8	15	–3
29	NV	23	4	33	5	10	1
30	OR, WA	35	12	41	7	6	–5
31	ID, UT	39	13	43	6	4	–7
32	CA	28	9	39	4	11	–5
33	HI	26	4	35	5	10	1
34	AK	37	11	35	5	–2	–6

Note: LIS (low-income subsidy), PDP (prescription drug plan). All calculations exclude plans offered in U.S. territories. Cumulative changes calculated from unrounded data.

Source: MedPAC analysis of CMS benchmark amounts and plan report data.

(Chart continued next page)

Chart 10-14 Part D benchmarks for LIS premiums and number of qualifying PDPs, by region (continued)

> Part D's LIS covers most premiums and cost sharing for enrollees with low incomes and assets. The LIS's coverage of premiums has a dollar limit, known as the benchmark, that encourages beneficiaries to enroll in lower-cost PDPs. Beneficiaries who enroll in plans with premiums that are less than the benchmark do not pay a premium; those who enroll in plans with higher premiums pay the difference. The PDPs for which LIS beneficiaries do not pay a premium are known as benchmark plans. When LIS beneficiaries do not select a PDP, Medicare automatically enrolls them in benchmark plans.

> The LIS benchmark equals the average premium for basic coverage in a region. CMS calculates it using a weighted average of both PDP and MA–PD premiums. For plans that offer enhanced coverage, CMS uses the portion of the plan's premium that reflects the cost of basic coverage only. For MA–PDs, CMS uses the amount of the premium for basic coverage before the plan sponsor has used any Part C (Medicare Advantage) rebates to reduce or eliminate the premium. The weight for each plan equals its share of LIS enrollment. CMS calculates separate benchmarks for each Part D region and updates them annually.

> In 2023, the lowest benchmark premium was $25 in Region 22 (Texas), for the fourth year in a row. Region 31 (Idaho and Utah) was joined by Region 16 (Wisconsin) and Region 28 (Arizona) for the highest benchmark premium in 2023 at $43 per month.

> The average benchmark premium across regions (not weighted by numbers of enrollees) has risen slowly over the years, from $31 per month in 2014 to $36 in 2023, an increase of 17 percent over 10 years (data not shown); this is in contrast to the average overall premium across all plans, weighted by enrollment, which decreased by 12 percent over the same period (see Chart 10-13).

> In 2014, the average number of benchmark plans in a region was 10; by 2023, that figure had dropped to 6, a decline of 46 percent (data not shown). The number of benchmark plans has declined or remained constant in every region over the past decade except Region 29 (Nevada) and Region 33 (Hawaii), both growing from four plans in 2014 to five in 2023. The overall decline is largely due to mergers and acquisitions among plan sponsors over the years. The maximum number of benchmark plans in any region in 2023 is 8, compared with 15 in 2014.

Chart 10-15 In 2023, about one in two listed drugs is subject to some utilization management

	Benchmark PDPs	PDP enrollees	MA–PD enrollees
5-tier formulary structure* (in percent)	100%	100%	99%
Drugs on formulary as % of all Part D drugs**	70%	74%	76%
Median cost-sharing amounts			
Tier 1: generic drugs	$1	$1	$0
Tier 2: other generic drugs	6	5	6
Tier 3: preferred brand-name drugs	33	44	47
Tier 4: nonpreferred drugs	39%	45%	$100
Tier 5: specialty-tier drugs	25%	25%	33%
Drugs with utilization management requirement (in percent)			
Prior authorization	31%	31%	28%
Step therapy	0	1	2
Quantity limits	42	42	43
Any utilization management	54	54	54

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Figures exclude employer-only groups and plans offered in U.S. territories. In addition, MA–PDs exclude demonstration programs, special needs plans, and 1876 cost plans. "Prior authorization" means that the enrollee must get preapproval from the plan before coverage. "Step therapy" refers to a requirement that the enrollee try specified drugs before being prescribed other drugs in the same therapeutic category. "Quantity limits" means that plans limit the number of doses of a drug available to the enrollee in a given time period. Generic drugs placed on Tier 1 are "preferred" (i.e., lowest cost sharing) relative to generic drugs placed on higher tiers, including Tier 2.
*Includes formularies with an additional (sixth) tier used for certain types of drugs (e.g., vaccines).
**Number of all Part D drugs is based on the counts of unique chemical entities listed on CMS's formulary reference file for the 2023 benefit year.

Source: MedPAC analysis of formularies submitted to CMS.

> In 2023, most Part D enrollees chose plans that have a five-tier structure: two generic, one preferred brand-name tier, and one nonpreferred drug tier (which may include both brand-name and generic drugs), plus a specialty tier.

> The number of drugs listed on a plan's formulary affects a beneficiary's access to medications. In 2023, on average, PDP enrollees have access to 74 percent of all Part D–covered products compared with 76 percent among MA–PD enrollees. That share was lower (70 percent) for beneficiaries enrolled in benchmark plans—basic PDPs for which LIS enrollees do not have to pay a premium.

> For enrollees in PDPs with a five-tier structure, the median copay in 2023 is $1 for a generic drug on a lower tier and $5 for other generic drugs. The median copay is $44 for a preferred brand-name drug and 45 percent coinsurance for a nonpreferred drug. Average cost-sharing amounts for benchmark plans are similar to other PDPs for generic drugs, but lower for brand-name drugs. For MA–PD enrollees, in 2023, the median copays for generic drugs are $0 and $6 for the two generic tiers, respectively. Both PDPs and MA–PDs use coinsurance (25 percent and 33 percent, respectively) for specialty-tier drugs.

> Plans' processes for nonformulary exceptions and use of utilization management tools—prior authorization (preapproval for coverage), quantity limits (limitations on the number of doses of a particular drug covered in a given period), and step therapy requirements (enrollees being required to try specified drugs before being prescribed other drugs in the same therapeutic category)—can affect access to certain drugs. In 2023, both PDPs and MA–PDs use some form of utilization management for 54 percent of drugs listed on a plan's formulary.

Chart 10-16 Components of Part D spending growth, 2014–2021

	2014	2021	Average annual growth 2014–2021
Total gross spending (in billions)	$121.4	$215.7	8.6%
High-cost beneficiaries	64.6	135.9	11.2%
Lower-cost beneficiaries	56.7	79.8	5.0%
Number of beneficiaries using a Part D drug (in millions)	37.1	47.7	3.6%
High-cost beneficiaries	3.4	4.1	2.5%
Lower-cost beneficiaries	33.7	43.6	3.7%
Amount per beneficiary who used Part D drugs			
Gross drug spending per year	$3,267	$4,525	4.8%
Average price per 30-day prescription	$60	$80	4.2%
Number of 30-day prescriptions	54.5	56.7	0.6%
Amount per high-cost beneficiary who used Part D drugs			
Gross drug spending per year	$18,845	$33,386	8.5%
Average price per 30-day prescription	$166	$291	8.4%
Number of 30-day prescriptions per month	9.6	9.7	0.1%
Amount per lower-cost beneficiary who used Part D drugs			
Gross drug spending per year	$1,683	$1,831	1.2%
Average price per 30-day prescription	$35	$36	0.4%
Number of 30-day prescriptions per month	4.2	4.5	0.8%

Note: "High-cost beneficiaries" refers to individuals who incurred spending high enough to reach the catastrophic phase of the benefit. "Gross spending" reflects payments to pharmacies from all payers, including beneficiary cost sharing, but does not include rebates and discounts from pharmacies and manufacturers that are not reflected in prices at the pharmacies. Changes in the average price per prescription reflect both price inflation and changes in the mix of drugs used. Components may not sum to totals due to rounding.

Source: MedPAC analysis of Part D prescription drug event data and common Medicare environment file from CMS.

> Between 2014 and 2021, gross spending on drugs under the Part D program grew by an annual average rate of 8.6 percent. The annual growth in spending was considerably higher (11.2 percent) among high-cost beneficiaries (individuals who incurred spending high enough to reach the catastrophic phase of the benefit) than among lower-cost beneficiaries (5.0 percent).

> During the 2014 through 2021 period, the number of high-cost beneficiaries grew more slowly (2.5 percent) compared with lower-cost beneficiaries (3.7 percent). The slower growth in the number of high-cost beneficiaries reflects the 25 percent increase in the out-of-pocket (OOP) threshold between 2019 and 2020. (For more information about the impact of the increase in the OOP threshold in 2020, see Chapter 13 of the Commission's March 2022 report to the Congress at https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch13_SEC.pdf.)

> The average price per 30-day prescription covered under Part D rose from $60 in 2014 to $80 in 2021. Overall, growth in price per prescription accounted for most (4.2 percentage points) of the 4.8 percent average annual growth in spending per beneficiary among beneficiaries who used Part D drugs. Growth in prices per prescription reflects increases in the prices of existing drugs and changes in the mix of drugs, including the adoption of new, higher-priced drugs.

> The average annual growth rate in overall spending per beneficiary reflects two distinct patterns of price and spending growth, one for high-cost beneficiaries and another for lower-cost beneficiaries. Among high-cost beneficiaries, annual growth in prices (8.4 percent) accounted for nearly all of the spending growth (8.5 percent) during this period. In contrast, among lower-cost beneficiaries, the increase (0.8 percent) in the number of prescriptions accounted for about two-thirds of the spending growth (1.2 percent).

Chart 10-17 Part D spending and use per enrollee, 2021

	Part D	Plan type		LIS status	
		PDP	MA–PD	LIS	Non-LIS
Total gross spending (billions)*	$215.7	$115.0	$100.7	$100.0	$115.6
Above OOP threshold (billions)	92.0	50.2	41.7	52.1	39.9
Share above OOP threshold	*43%*	*44%*	*41%*	*52%*	*35%*
Total number of prescriptions (millions)	2,704	1,326	1,378	909	1,795
Average spending per prescription	$80	$87	$73	$110	$64
Share of beneficiaries with no drug use	7%	7%	6%	8%	6%
Per enrollee per month					
Total spending	$368	$396	$340	$631	$271
OOP spending	31	38	23	5	40
Manufacturer gap discount	25	30	20	N/A	34
Plan liability	243	256	230	428	174
Low-income cost-sharing subsidy	53	53	54	197	N/A
Number of prescriptions	4.6	4.6	4.7	5.7	4.2

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income subsidy), OOP (out-of-pocket), N/A (not applicable). "Total gross spending" reflects payments from all payers, including beneficiaries (cost sharing) but does not include rebates and discounts from pharmacies and manufacturers that are not reflected in prices at the pharmacies. "Plan liability" includes plan payments for drugs covered by both basic and supplemental (enhanced) benefits. "Number of prescriptions" is standardized to a 30-day supply. Components may not sum to totals due to rounding.
*"Total gross spending" includes $14.6 billion in manufacturer discounts for brand-name drugs and biologics filled by non-LIS enrollees during the coverage gap.

Source: MedPAC analysis of Medicare Part D PDE data and common Medicare environment file from CMS.

> In 2021, gross spending on drugs for the Part D program totaled $215.7 billion, with about 53 percent ($115 billion) accounted for by Medicare beneficiaries enrolled in stand-alone PDPs. Part D enrollees receiving the LIS accounted for about 46 percent ($100 billion) of the total. Manufacturer discounts for brand-name drugs filled by non-LIS enrollees while they were in the coverage gap accounted for 6.8 percent of the total, or 12.6 percent of the gross spending by non-LIS enrollees (up from 6.3 percent and 11.9 percent, respectively, in 2020; data not shown).

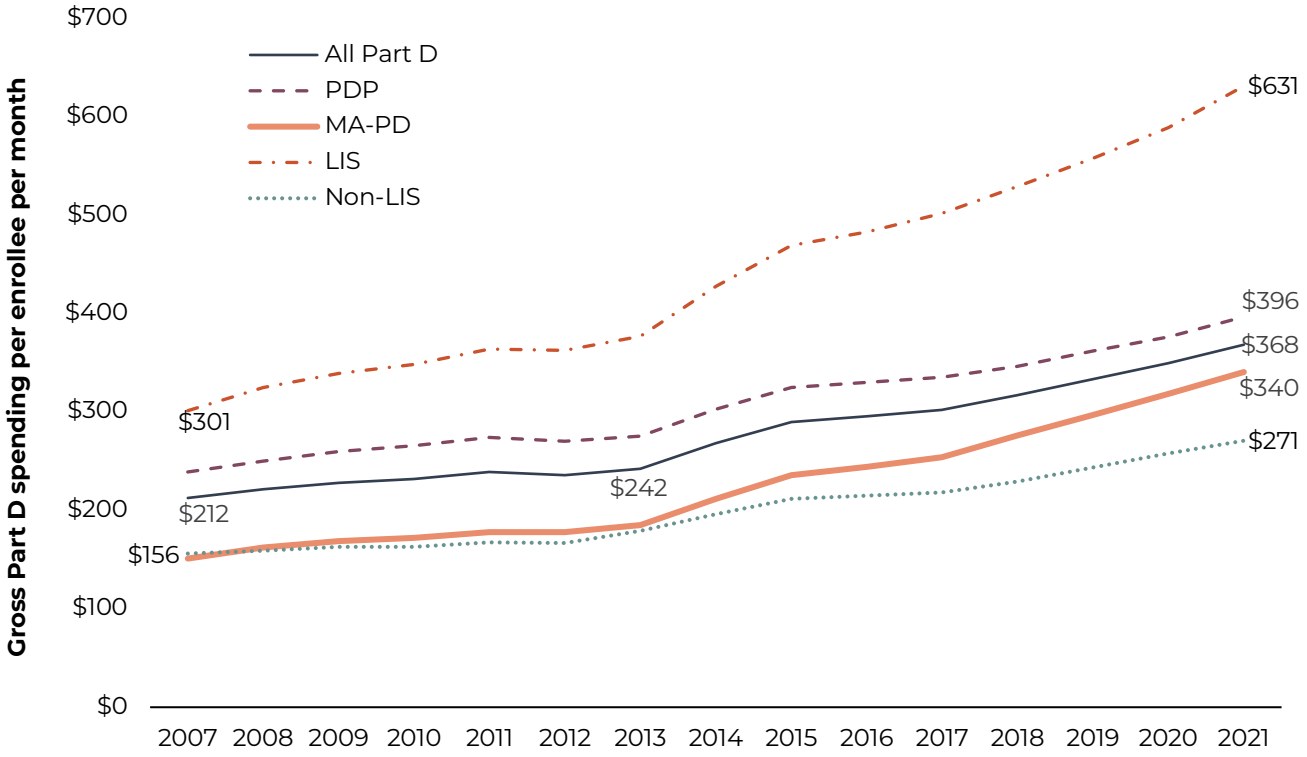
> Overall, 43 percent of gross spending was incurred after a beneficiary reached the annual OOP threshold ($6,550 in 2021). That share was higher among those who received the LIS (52 percent) compared with other enrollees (35 percent).

> The number of prescriptions filled by Part D enrollees totaled 2.7 billion, with 49 percent (1.3 billion) accounted for by PDP enrollees. The 28 percent of enrollees who received the LIS accounted for about 34 percent (909 million) of the total number of prescriptions filled. Overall, 7 percent of Part D enrollees did not fill any prescriptions during the year.

> In 2021, Part D enrollees filled 4.6 prescriptions at $368 per month on average, an increase from $349 per month (for 4.6 prescriptions) in 2020 (2020 data not shown). The average monthly plan liability for PDP enrollees ($256) was higher than that of MA–PD enrollees ($230). The average monthly OOP spending was smaller for MA–PD enrollees than PDP enrollees ($23 vs. $38, respectively). The average monthly low-income cost-sharing subsidy for MA–PD enrollees exceeded that of PDPs for the first time in 2021 ($53 vs. $54).

> Average monthly spending per LIS enrollee ($631) was more than double that of a non-LIS enrollee ($271), and the average number of prescriptions filled per month by an LIS enrollee was 5.7 compared with 4.2 for a non-LIS enrollee. LIS enrollees had much lower monthly OOP spending, on average, than non-LIS enrollees ($5 vs. $40, respectively). Part D's LIS pays for most of the cost sharing for LIS enrollees, averaging $197 per month in 2021.

Chart 10-18 Trends in Part D spending and use per enrollee per month, 2007–2021



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income subsidy). "Spending" (gross) reflects payments from all payers, including beneficiaries (cost sharing) but does not include rebates and fees from manufacturers and pharmacies that are not reflected in prices at the pharmacies.

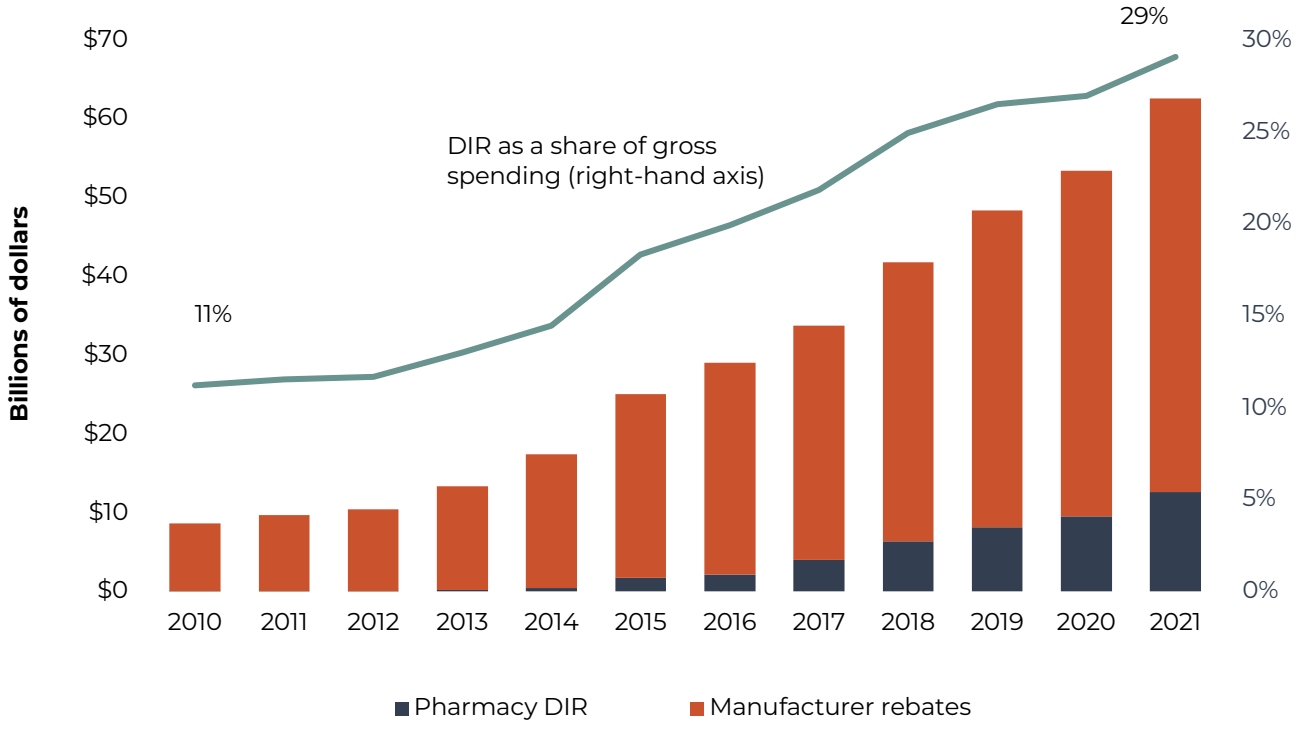
Source: MedPAC analysis of Medicare Part D PDE data and Part D denominator file from CMS.

> Between 2007 and 2021, average per capita spending per month for Part D–covered drugs grew from $212 to $368, an average growth rate of 4.0 percent annually, or about 73 percent cumulatively. The rate of growth in average per capita spending more than doubled after 2013, in part reflecting the introduction of new hepatitis C treatments in 2014 and other new expensive therapies in subsequent years.

> Between 2007 and 2021, monthly per capita spending for LIS enrollees grew faster than that for non-LIS enrollees, increasing from $301 to $631 (a cumulative growth of over 109 percent) compared with an increase from $156 to $271 for non-LIS enrollees (a cumulative growth of 73 percent). The number of prescriptions filled by both LIS and non-LIS enrollees grew by just under 2 percent annually during this period (data not shown).

> The growth in monthly per capita drug spending among MA–PD enrollees exceeded that of PDP enrollees during the 2007 to 2021 period (annual average growth of 6.0 percent and 3.7 percent, respectively). The average per capita spending for MA–PD enrollees continued to be lower than that of PDP enrollees (by $56 per month in 2021); however, that difference has been declining since 2014.

Chart 10-19 DIR expanded rapidly in Part D, 2010–2021



Note: DIR (direct and indirect remuneration). "Gross spending" includes enrollee cost sharing and plan (and any other) payments to the pharmacy at the point of sale for both brand and generic prescriptions. Pharmacy DIR consists of net postsale payments from pharmacies to plan sponsors and their pharmacy benefit managers.

Source: MedPAC analysis of prescription drug event data and DIR data.

> The final amounts that Part D plans pay for their enrollees' prescriptions are often lower than prices at the pharmacy because plan sponsors and their pharmacy benefit managers (PBMs) negotiate postsale rebates and fees from drug manufacturers and pharmacies; CMS refers to those amounts as direct and indirect remuneration (DIR). Medicare keeps a portion of DIR to offset some of its reinsurance subsidies to plans. While large rebates help to constrain premium increases, using rebates primarily to lower premiums also means that beneficiaries who use such drugs (or the Medicare program, in the case of Part D's low-income subsidy (LIS) enrollees) sometimes pay cost sharing that is a significant portion of—and may even be higher than—the drug's cost to the plan. For enrollees without the LIS, high cost sharing can affect whether they fill their prescriptions.

> Between 2010 and 2021, DIR ballooned from $8.6 billion to $62.7 billion. With manufacturer rebates accounting for roughly 23 percent of gross Part D spending in 2021 and pharmacy DIR another 6 percent, total DIR equaled about 29 percent, up from 11 percent in 2010.

> Multiple factors have contributed to growth in manufacturer rebates. For certain classes of drugs that lack of generic competition but have considerable rivalry among competing brands, manufacturers have chosen to raise gross prices and compete using postsale rebates. Due to Part D's unusual benefit design and its emphasis on premium competition, sponsors have had incentives to try to maximize rebates and keep premiums low. Vertically integrated insurers with their own PBMs and specialty and mail-order pharmacies have large market shares of enrollment and dispensing, which tends to provide those plan sponsors with greater bargaining leverage for postsale price concessions from both manufacturers and pharmacies.

Chart 10-20 Incidence of Part D spending by type of product, 2021

			Share of gross spending paid					
			Medicare (at risk)			Pharmaceutical manufacturers		
	Total gross spending	Part D plans (at risk)	Reinsurance	Low-income subsidy	Beneficiary cost sharing	Coverage gap discount	Postsale rebates and discounts	Pharmacy fees
Brand-name drugs	$132.8	14%	27%	13%	6%	8%	26%	5%
Biologics	42.9	6	30	12	4	8	33	6
Generic drugs	38.1	39	9	21	21	N/A	<1	9
All products covered under Part D*	215.7	17	24	14	9	7	23	6

Note: "Total gross spending" reflects payment from all payers, including beneficiaries (through cost sharing) before accounting for postsale rebates, discounts, and fees from pharmacies and manufacturers. "Biologics" includes spending for insulins.
*Includes some products that could not be classified as one of the three drug types shown (e.g., nondrug products such as syringes used for insulins).

Source: MedPAC analysis of prescription drug event data and direct and indirect remuneration data.

> In 2021, just over 80 percent of total gross Part D spending was for brand-name drugs ($132.8 billion, or 62 percent) or biologics ($42.9 billion, or 20 percent). Generic drugs accounted for about 18 percent ($38.1 billion) of gross spending.

> The incidence of Part D spending varied by drug type, with Medicare's reinsurance accounting for a larger share of spending for brand-name drugs and biologics compared with generic drugs. For example, plans were at risk for 6 percent of biologics spending (including biosimilars) compared with 30 percent for Medicare's reinsurance. In contrast, for generic drugs, Medicare's reinsurance accounted for 9 percent of gross spending compared with 39 percent for plans. Medicare's low-income subsidy, on average, accounted for a higher share of gross spending for generic drugs (21 percent) compared with brand-name drugs (13 percent) or biologics (12 percent).

> On average, beneficiaries' cost sharing accounted for 21 percent of gross spending for generic drugs compared with 6 percent for brand-name drugs and 4 percent for biologics. Cost sharing as a share of gross spending tends to be lower for brand-name drugs and biologics because these products are more likely to be filled in the catastrophic phase of the benefit, where a lower coinsurance rate applies (5 percent of gross prices at the pharmacy) than for other phases of the benefit (typically averaging 25 percent of gross prices at the pharmacy). However, because prices of brand-name drugs and biologics are much higher than those of generic drugs, the lower coinsurance rate could still result in substantially higher cost-sharing liability than for generic drugs.

> Coverage-gap discount and postsale rebates and fees paid by pharmaceutical manufacturers accounted for 7 percent and 23 percent of gross spending, respectively, across all Part D–covered products. Nearly all of those payments were for brand-name drugs and biologics. Pharmacy fees accounted for the remaining 6 percent of gross spending. On average, pharmacy fees accounted for a higher share of gross spending for generic drugs (9 percent) than for brand-name drugs (5 percent) or biologics (6 percent).

Chart 10-21 Top 15 therapeutic classes of drugs covered under Part D, by spending, 2021

	Gross spending		Negotiated rebates as a share of gross spending	Coverage-gap discount (billions)
	Billions	Percent		
Diabetic therapy	$39.7	18.4%	≥50%	$5.2
Antineoplastics	28.8	13.4	<10%	0.8
Anticoagulants	18.6	8.6	40% to 49%	3.1
Asthma/COPD therapy agents	15.5	7.2	40% to 49%	1.4
Disease-modifying anti-rheumatoid drugs	10.4	4.8	20% to 29%	0.4
Antipsychotics (neuroleptics)	7.5	3.5	10% to 19%	0.1
Antiretrovirals	7.3	3.4	<10%	0.2
Antihypertensive therapy agents	6.9	3.2	10% to 19%	0.4
Ophthalmic agents	5.6	2.6	30% to 39%	0.4
Antihyperlipidemics	5.0	2.3	10% to 19%	0.3
Multiple sclerosis agents	4.5	2.1	10% to 19%	0.1
Anticonvulsants	4.2	2.0	<10%	0.1
Dermatological (antipsoriatics)	3.6	1.7	10% to 19%	0.1
Antidepressants	2.9	1.3	<10%	0.1
Urinary incontinence treatment agents	2.7	1.2	40% to 50%	0.3
Subtotal, top 15 drug classes	163.2	75.7	27%	12.8
Total all drug classes	215.7	100.0	23%	14.6

Note: COPD (chronic obstructive pulmonary disease). "Gross spending" reflects payments from all payers, including beneficiaries (cost sharing) for both brand and generic drugs but does not include rebates and discounts from pharmacies and manufacturers that are not reflected in prices at the pharmacies. Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System. Components may not sum to totals due to rounding.

Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

> In 2021, the top 15 therapeutic classes by spending accounted for nearly 76 percent of the $215.7 billion spent on prescription drugs covered by Part D plans.

> In 2021, total manufacturer rebates as a share of gross spending ranged from less than 10 percent to more than 50 percent. Some of that variation reflects the degree of competition within each therapeutic class. Overall, rebates for the top 15 classes averaged 27 percent of gross spending, higher than the average of 23 percent for all Part D spending. Rebates were the highest (greater than or equal to 50 percent) for diabetic therapies, which accounted for more than 18 percent of total gross spending in Part D.

> In addition to negotiated rebates, manufacturers must provide discounts for brand-name drugs and biologics filled by non-LIS enrollees when they fill prescriptions in the coverage-gap phase of the benefit. In 2021, these top 15 classes accounted for 88 percent ($12.8 billion) of all coverage-gap discounts. Diabetic therapies alone accounted for more than one-third of all coverage-gap discounts.

Chart 10-22 Despite high generic use, brand-name drugs accounted for the majority of spending in the top 15 therapeutic classes by spending, 2021

	Prescriptions*		Generic dispensing rate	Brand share of gross spending	LIS share of prescriptions
	Millions	Percent			
Diabetic therapy	191.8	7.1%	61%	97%	31%
Antineoplastics	15.0	0.6	86	95	21
Anticoagulants	54.0	2.0	26	99	26
Asthma/COPD therapy agents	81.1	3.0	53	91	43
Disease modifying anti-rheumatoid drugs	2.7	0.1	35	99	48
Antipsychotics (neuroleptics)	34.4	1.3	90	81	68
Antiretrovirals	3.1	0.1	18	97	68
Antihypertensive therapy agents	276.8	10.2	99	63	18
Ophthalmic agents	59.5	2.2	79	79	27
Antihyperlipidemics	309.1	11.4	98	44	18
Multiple sclerosis agents	0.8	<0.1	31	91	54
Anticonvulsants	103.7	3.8	98	50	45
Dermatological (antipsoriatics)	0.7	<0.1	36	98	54
Antidepressants	174.9	6.5	99	27	32
Urinary incontinence treatment agents	19.7	0.7	72	82	36
Subtotal, top 15 drug classes	1,327.3	49.1	85	89	28
Total, all drug classes	2,703.1	100.0	90	81	27

Note: COPD (chronic obstructive pulmonary disease), LIS (low-income subsidy). "Gross spending" reflects payments from all payers, including beneficiaries (cost sharing) for both brand and generic drugs but does not include rebates and discounts from pharmacies and manufacturers that are not reflected in prices at the pharmacies. Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System. Components may not sum to totals due to rounding.
*Prescriptions are standardized to a 30-day supply.

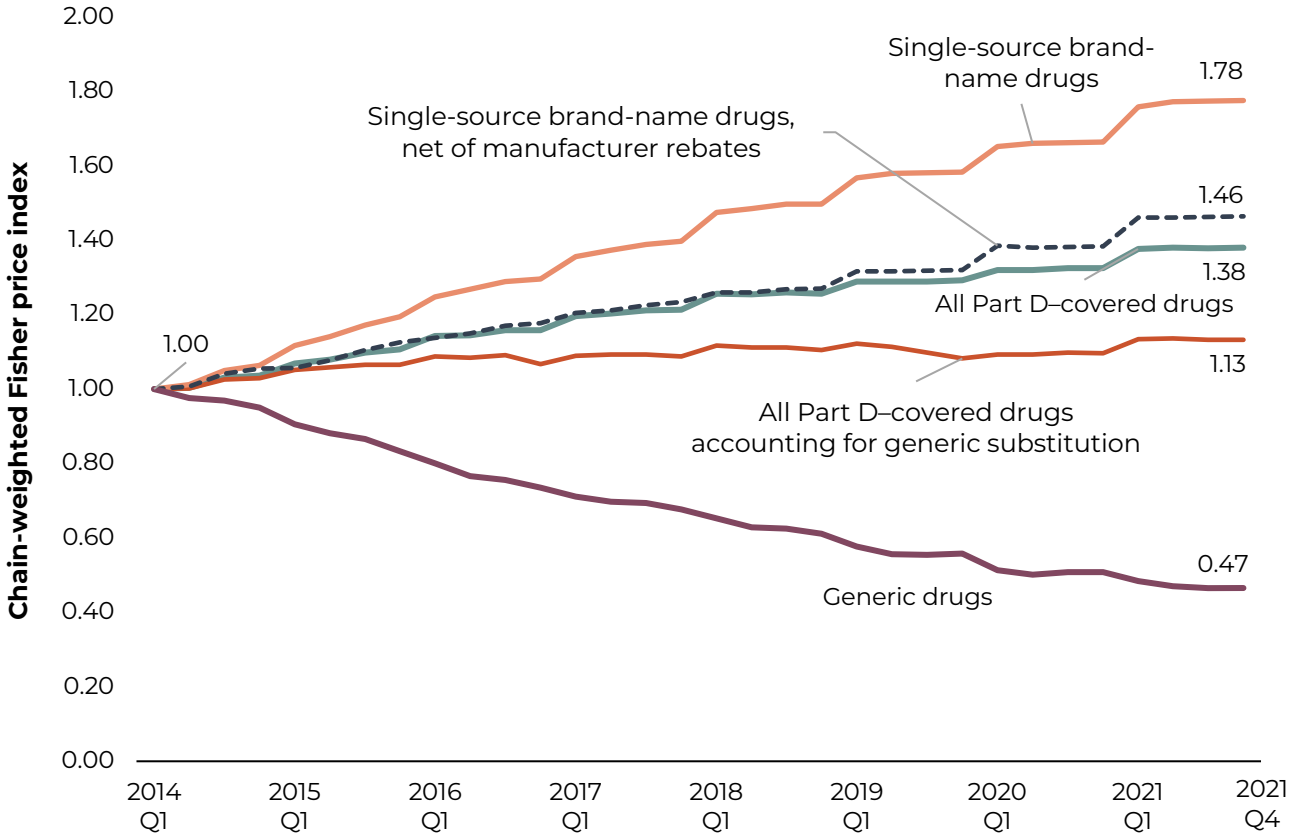
Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS.

> Prescriptions filled in the top 15 therapeutic classes by spending in 2021 (from Chart 10-20) totaled more than 1.3 billion prescriptions, accounting for nearly half of all prescriptions filled under Part D. While 85 percent of these prescriptions were for generic drugs, brand-name products accounted for 89 percent of the gross spending for these products in 2021.

> In 2021, LIS beneficiaries filled 28 percent of total prescriptions for products in these 15 classes, roughly equal to their share of prescriptions among all Part D drugs (27 percent). Nevertheless, LIS enrollees accounted for a disproportionate share of prescriptions in a few classes such as antipsychotics (68 percent) and antiretrovirals (68 percent).

> Even when generic drugs are widely used by Part D beneficiaries, for some therapeutic classes, brand-name drugs may still account for the vast majority of spending. For example, in 2021, generic drugs accounted for 86 percent of prescriptions for antineoplastics, but brand-name drugs accounted for 95 percent of gross spending for that class.

Chart 10-23 **Price growth for Part D–covered drugs, 2014–2021**



Note: Q1 (first quarter), Q4 (fourth quarter). Unless noted otherwise, Part D indexes reflect total amounts paid to pharmacies and do not reflect retrospective rebates or discounts from manufacturers and pharmacies.

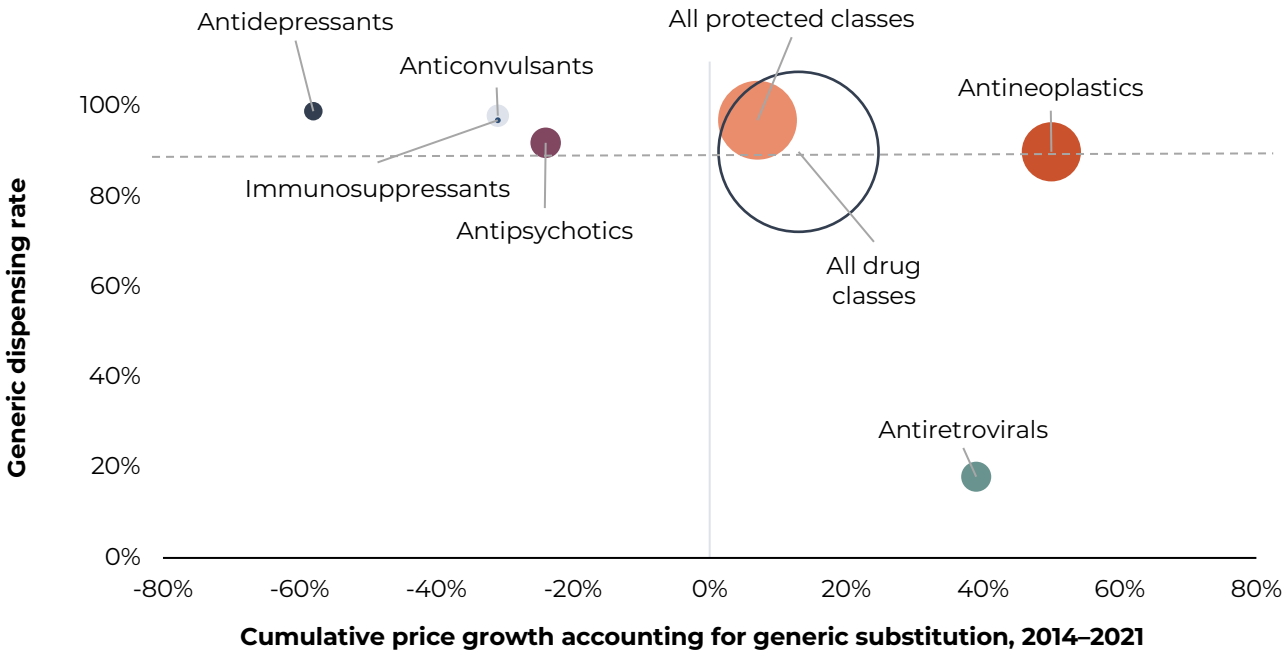
Source: Acumen LLC analysis for MedPAC.

> Measured by individual national drug codes, prices of drugs and biologics covered under Part D rose 38 percent cumulatively between 2014 and 2021 (an index of 1.38). (Prices reflect total amounts paid to pharmacies and do not reflect retrospective rebates or discounts from manufacturers and pharmacies.)

> Overall, between 2014 and 2021, prices of generic drugs covered under Part D decreased to 47 percent of the average price observed at the beginning of 2014. As a result, when measured by a price index that takes generic substitution into account, Part D prices have remained relatively flat during this period, with cumulative increase in prices at the end of 2021 at 13 percent above the prices at the beginning of 2014 (an index of 1.13). New and increased generic competition for selected therapeutic classes, such as anticonvulsants, antineoplastics, and drugs for multiple sclerosis, played a key role in slowing the growth in overall Part D prices during this period.

> Between 2014 and 2021, prices for all single-source, brand-name drugs (drugs with no generic substitutes) grew by a cumulative 78 percent (an index value of 1.78), compared with 46 percent (an index value of 1.46) for prices net of manufacturer rebates.

Chart 10-24 Price growth for therapeutic classes with protected status under Part D after accounting for generic substitution, 2014–2021



Note: Price indexes reflect total amounts paid to pharmacies and do not reflect retrospective rebates or discounts from manufacturers and pharmacies. The size of the bubble for each drug class reflects its relative share of gross spending in 2021.

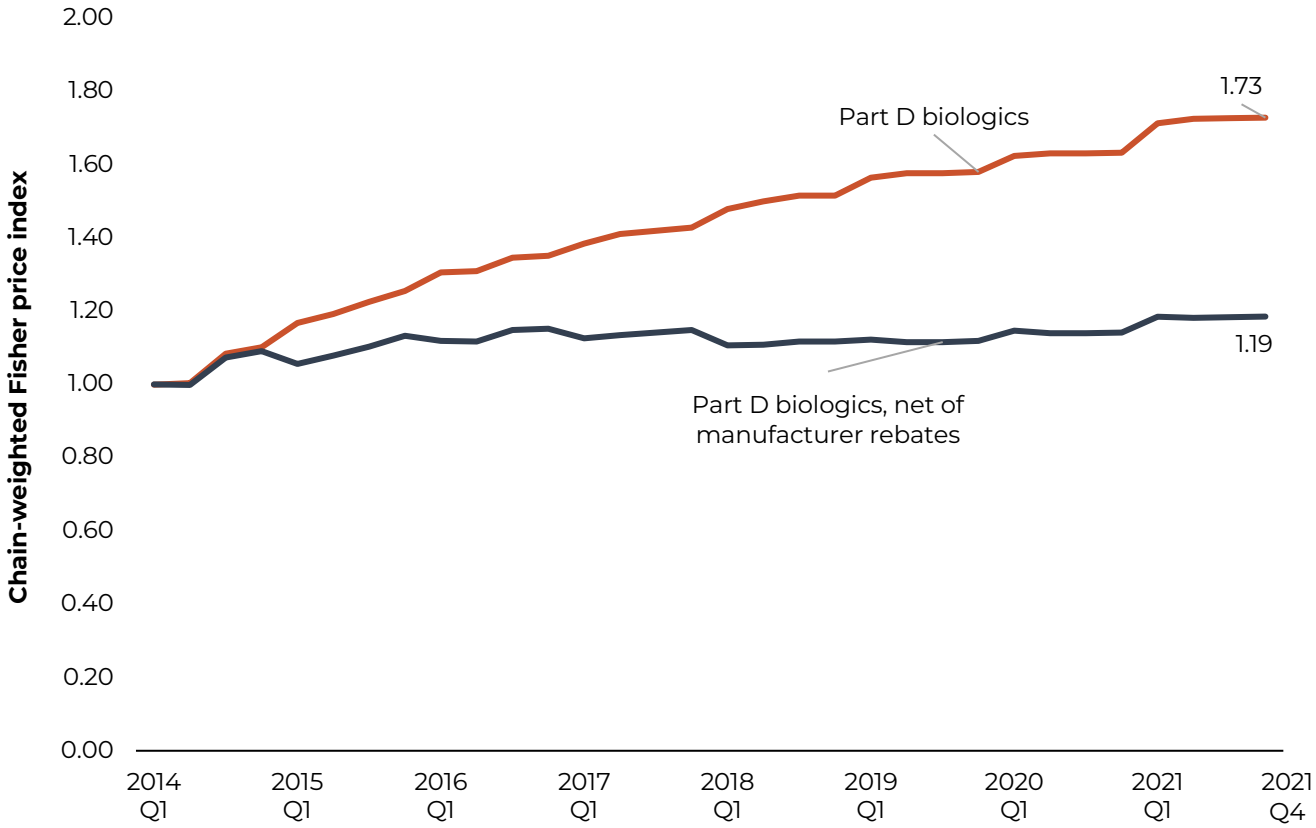
Source: MedPAC analysis of Medicare Part D prescription drug event and direct and indirect remuneration data from CMS and Acumen LLC for MedPAC.

> Medicare Part D designates six “protected classes" for which plan sponsors must include “all or substantially all” available drugs on their formularies: antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics. This policy provides patients with broader access to products, but it may also give manufacturers greater market power to raise prices for drugs already on the market or set high prices for new drugs. However, there are considerable differences across the six protected classes in the competitive pressures and how generic substitution affects pricing trends.

> Between 2014 and 2021, measured by individual national drug codes, cumulative price growth for all drugs in each of the protected classes, after accounting for generic substitution, ranged from −58 percent for antidepressants to 50 percent for antineoplastics. (Prices reflect total amounts paid to pharmacies and do not reflect retrospective rebates or discounts from manufacturers and pharmacies.)

> The availability of generics varies considerably across the protected classes, and widespread use of generics can influence overall price growth. For most protected classes, generic dispensing rates (GDRs) are high and thus prices have fallen considerably over time. Antineoplastics stand out as an exception: Despite a GDR of 90 percent, prices for the class grew 50 percent between 2014 and 2021, even after accounting for generic substitution (see the Commission’s June 2023 report for more).

Chart 10-25 Price growth for biologics covered under Part D, 2014–2021



Note: Q1 (first quarter), Q4 (fourth quarter). Part D biologics indexes were constructed using total amounts paid to pharmacies with and without retrospective rebates and discounts from manufacturers. Biologics include insulins. The indexes do not reflect retrospective fees and discounts from pharmacies.

Source: Acumen LLC analysis for MedPAC.

> Measured by individual national drug codes, prices of biologics (without retrospective rebates, fees, or discounts) covered under Part D rose 73 percent cumulatively between 2014 and 2021 (an index of 1.73). This increase is similar to the growth in prices for all single-source drugs and biologics (78 percent, or an index value of 1.78). (See Chart 10-23 for index measuring prices of all single-source drugs and biologics.)

> In comparison, between 2014 and 2021, prices of biologics net of retrospective rebates and discounts from manufacturers grew by a cumulative 17 percent (an index value of 1.19). The effect of manufacturer rebates on the prices of biologics was greater than that for all single-source drugs and biologics, which grew by a cumulative 46 percent (an index value of 1.46) for prices net of manufacturer rebates. (See Chart 10-23 for index measuring prices of all single-source drugs (including biologics) net of manufacturer rebates.)

> The prices of biologics are highly influenced by the prices of insulins. In 2021, insulins accounted for about 36 percent of total gross spending on biologics. Insulins and other antidiabetic therapies had some of the highest rebates, totaling more than 50 percent of gross spending for therapies in that class (see Chart 10-21).

Chart 10-26 Part B and Part D spending on products with a biosimilar pipeline

Brand name	Earliest biosimilar launch date (expected)	Number of biosimilars: Approved	Number of biosimilars: In pipeline	2021: Part B spending on originator product (billions)	2021: Part D spending on originator product (billions)	2021: Total Part B and Part D spending on biosimilars (billions)
Products with an approved biosimilar on the market						
Neupogen[a]	2015	3	1–3	$0.02	$0.01	$0.08
Remicade	2016	4	1–3	0.51	0.10	0.15
Procrit/Epogen	2018	1	1–3	0.06	0.14	0.12
Neulasta	2018	6	1–3	0.52	0.06	0.37
Humalog[a]	2018	2	1–3	**	1.70	0.28
Humalog Mix (75/25)[a]	2019	1		**	0.33	0.02
Rituxan	2019	3	4–6	0.83	0.05	0.55
Avastin	2019	4	4–6	0.37	0.02	0.52
Herceptin	2019	5	4–6	0.24	0.01	0.29
Lantus[ab]	2020	3	1–3	–	3.79	0.71
Novolog[a]	2020	1	4–6	–	2.37	0.08
Novolog Mix (50/50)[a]	2020	1	1–3	–	0.48	0.01
Lucentis[b]	2022	2	1–3	1.04	0.00	–
Humira[b]	2023	8	4–6	–	4.73	–
Subtotal				*3.60*	*13.83*	*3.18*
Products with a biosimilar approved but not yet on the market						
Enbrel	(2028)	2	1–3	–	2.36	–
Products with a biosimilar in development but none approved						
Stelara			7+	0.27	1.57	–
Toujeo			1–3	–	0.83	–
Soliris			1–3	0.64	0.25	–
Cimzia			1–3	0.50	0.22	–
Actemra			4–6	0.29	0.22	–
Simponi			1–3	0.37	0.17	–
Xolair			4–6	0.40	0.16	–
Tysabri			1–3	0.21	0.04	–
Eylea			7+	3.42	0.03	–
Prolia/Xgeva			7+	1.78	0.47	–
Subtotal				*7.87*	*3.95*	–
TOTAL		41	87	11.47	20.15	3.18

Note: Products included in this analysis include those approved or known to be in development as of May 2023.
[a]Authorized generics and follow-on products are included as biosimilars for purposes of this analysis. For a list of biosimilars currently on the market and available under Part B, refer to Chart 10-5. Others included in this analysis: Avastin: Alymsys, Vegzelma; Enbrel: Erelzi, Eticovo; Humalog: Admelog, insulin lispro AG; Humalog Mix (75/25): insulin lispro-protamine mix AG; Humira: Amjevita, Cyltezo (INT), Hyrimoz, Hadlima, Abrilada, Hulio, Yusimry, Idacio; Lantus: Basaglar, Semglee (INT), Rezvoglar; Lucentis: Cimerli; Neulasta: Fylnetra, Stimufend; Neupogen: Releuko; Novolog: insulin aspart AG; Novolog Mix (50/50): insulin aspart protamine AG.
[b]At least one biosimilar for this reference product has been designated by the Food and Drug Administration as interchangeable.
**Not able to distinguish spending on Humalog from other insulin lispro products in Part B.

Source: MedPAC analysis of CMS Drug Spending Dashboard, Food and Drug Administration Purple Book, and U.S. Biosimilar Report from AmerisourceBergen.

(Chart continued next page)

Chart 10-26 Part B and Part D spending on products with a biosimilar pipeline (continued)

> The first biosimilar product licensed under the Public Health Service Act was launched in the U.S. in 2015. As of May 2023, the Food and Drug Administration (FDA) has approved 46 biological products to compete with innovator biologics (40 biosimilars and 6 follow-on or authorized generic insulin products). Also as of May 2023, manufacturers have launched 44 biosimilars in the U.S., and another 84 are in development.

> Given that generic dispensing rates have plateaued since 2017 at roughly 90 percent, it is likely that any significant savings on drug spending in the future will come from the successful launch and adoption of biosimilars rather than increased use of traditional generic drugs. This chart shows the high level of spending on biological products for which biosimilars have or may soon enter the market and offer competition to potentially reduce spending.

> In 2021, Medicare spent $17.4 billion ($3.6 billion in Part B and $13.8 billion in Part D) on originator drugs for which biosimilars are now available; this includes spending on Lucentis and Humira, though their biosimilars did not become available until after 2021. Medicare spent another $2.36 billion in Part D on drugs for which the FDA has approved biosimilars but manufacturers have not yet launched their products on the market. Spending on products for which biosimilars are in development but none are yet approved equaled $11.83 billion ($7.87 billion in Part B and $3.95 billion in Part D). In 2021, these products combined accounted for 14 percent of all Medicare spending for separately payable drugs in Part B and Part D.

> In 2021, $3.18 billion was spent on biosimilars, with 61 percent ($1.9 billion) of that spending (data not shown) occurring in Part B. With more biosimilars for top-selling Part D drugs recently launching (including Humira in 2023), this share is likely to shift somewhat; however, the current biosimilar pipeline still favors drugs predominantly covered under Part B.