MILLIMAN RESEARCH REPORT

Five-year analysis of the Drug Pricing Lab's Production Plus Profit Pricing (P-quad) proposal for biologic drugs

Commissioned by the Drug Pricing Lab at Memorial Sloan Kettering Cancer Center

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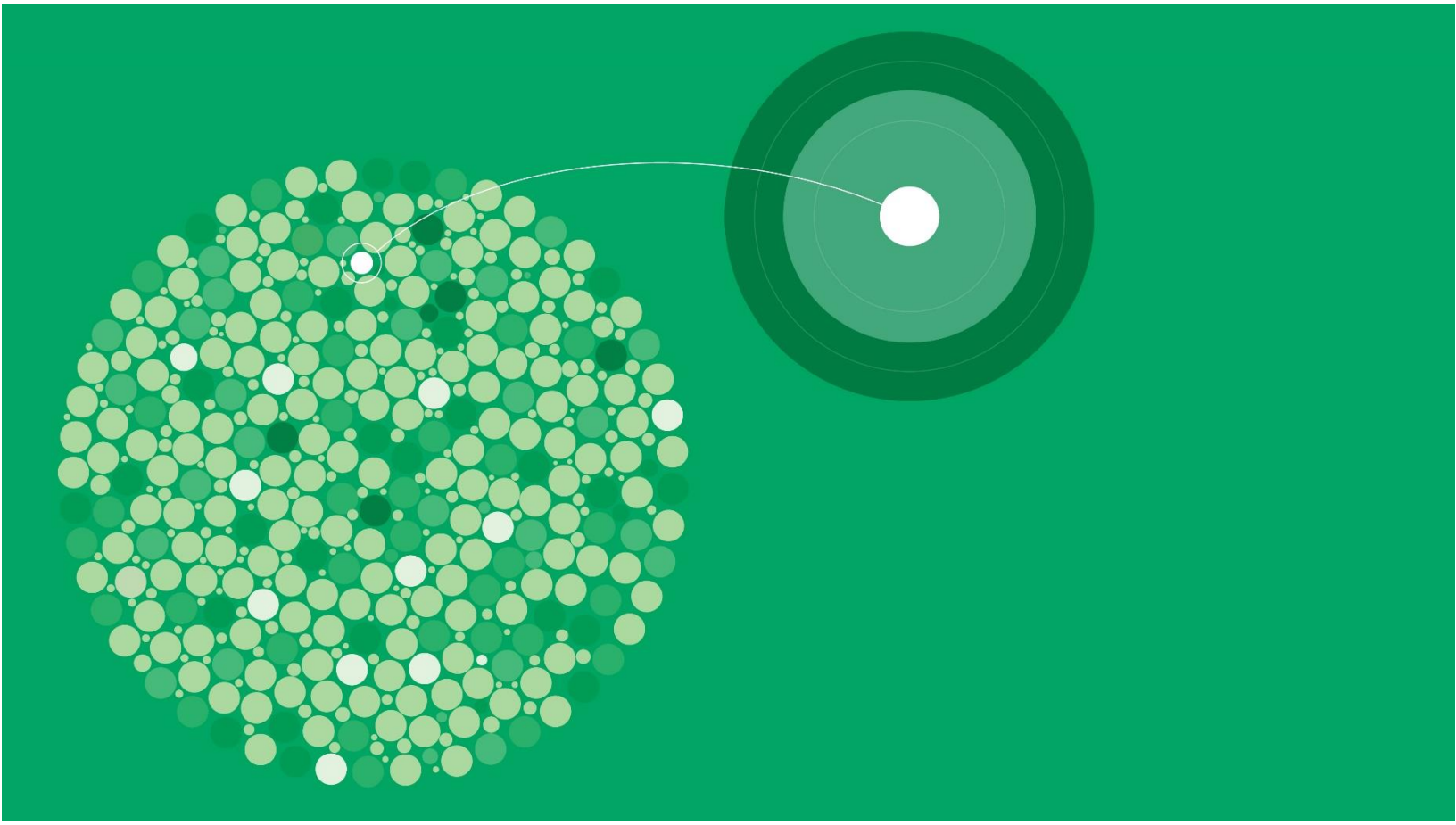
Kevin Pierce, FSA, MAAA
Dustin Pollastro, PharmD, MBA



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Executive Summary

Biologic drugs reflect a growing portion of healthcare spend. In 2019, gross biologic spend reached $211 billion in the United States (based on invoice-level medical spend). Gross biologic spend increased by 14.6% annually from 2015 to 2019, and biologics account for 48% of net drug spend (based on manufacturer net revenue).[1]

The Drug Pricing Lab at Memorial Sloan Kettering developed a proposal for setting U.S. biologic and biosimilar drug prices using what it refers to as Production Plus Profit Pricing (P-quad).[2] The P-quad proposal would set biologic drug prices based on production costs plus a fixed profit margin following completion of the initial FDA granted exclusivity period (or upon market entry for biosimilars). The Drug Pricing Lab engaged Milliman to estimate projected U.S. biologic and biosimilar drug spend from 2021 to 2025 under the current biosimilar competitive model compared to the same under the P-quad proposal. This report describes our analysis and results. Milliman does not endorse any public policy or advocacy position on matters discussed in this report or otherwise.

The pharmaceutical industry is complex with numerous stakeholders. In this paper, we evaluate federal government, plan sponsor, and beneficiary drug spend. We do not quantify the impact on other stakeholders including providers, drug manufacturers, pharmacy benefit managers (PBMs), other intermediaries, and non-U.S. stakeholders.

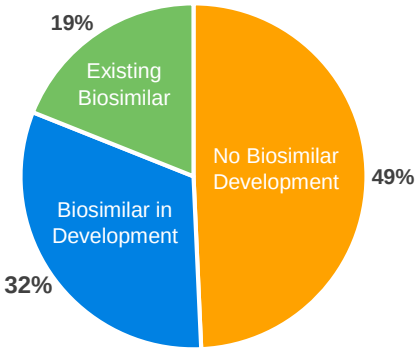
WHAT ARE BIOLOGICS AND BIOSIMILARS?

- **Biologic drugs** are a diverse category of products and are generally large, complex molecules.[3] Examples include autoimmune, oncology or cancer, and diabetic insulin products. Biologic products compete with each other and biosimilars for market volume.
- **Biosimilar** drugs are biologics that are highly similar to and have no meaningful clinical differences from an existing reference biologic. Like generic alternatives to brand drugs, biosimilars introduce product competition after a period of exclusivity for an innovator biologic. However, biosimilars are different from generics, as they are more complex to manufacture, are not identical replicas, and generally have higher net prices than generics.[4]

After a biologic drug's patent expires, approved biosimilars can enter the market. Many biologics with existing patents extended their market exclusivity periods after their initial patent approvals. The average sales price (ASP) for existing biosimilars is 30% lower than reference biologics on average (as of July 2020).[5] Both reference biologic and biosimilar manufacturers may also offer rebates as a response to competition. In these ways, competition from existing biosimilars may decrease drug spend.

As of October 2020, the FDA has approved 28 biosimilars, of which 20 are available in the United States. In addition, more than 100 future biosimilars are currently in development across 22 reference biologics.[6] Figure 1 illustrates the proportion of 2019 biologic spend associated with each biosimilar development status.

FIGURE 1: PERCENTAGE OF 2019 BIOLOGIC SPENDING BY BIOSIMILAR COMPETITION AND DEVELOPMENT STATUS



2019 Biologic Spending Breakdown

- **Products with no biosimilar in development** reflect 49% ($104 billion) of biologic spending
- **Products with biosimilars in development** reflect 32% ($67 billion) of biologic spending
- **Products with existing biosimilars** reflect 19% ($40 billion) of biologic spending

Source: "Biosimilars in the United States 2020-2024." IQVIA. Published October 2020

For products with and without biosimilars in development, spending is allocated into a few subcategories defined below.

- **Biologics without biosimilar in development**: Of the $104 billion shown in Figure 1, $8 billion is for products with expired patents, $10 billion is for products with patents set to expire by 2025, and $86 billion is for products with patents set to expire after 2025.
- **Biologics with biosimilar in development**: Of the $67 billion shown in Figure 1, $6 billion is for products with expired patents, $55 billion is for products with patents set to expire by 2025, and $6 billion is for products with patents set to expire after 2025.

WHAT MAY BE THE IMPACT TO U.S. DRUG SPEND?

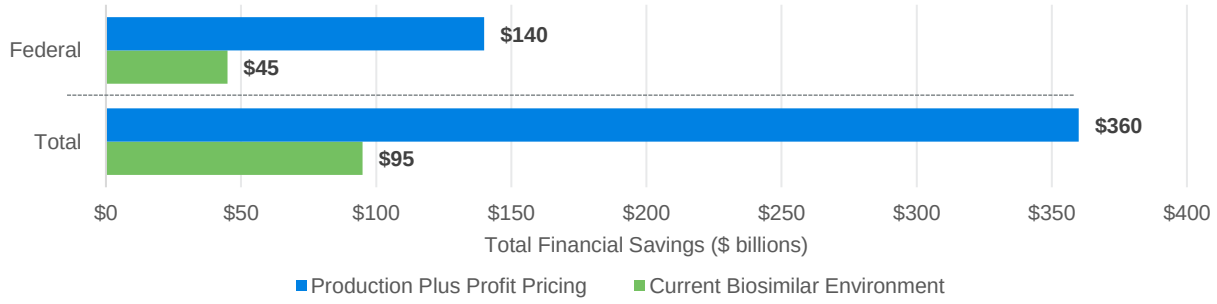
We projected U.S. biologic spend by drug for payers and beneficiaries from 2021 to 2025 under three different scenarios, as described below. We estimated spend separately by market (group, Medicare Part B, Medicare Part D, Medicaid, and individual) and allocated costs by stakeholder for each of the following scenarios:

- **No biosimilars**: This scenario assumes the biosimilar market does not exist and has never existed. We assume biologic prices are consistent with the "status quo" scenario before a biosimilar launches. This scenario provides a baseline to estimate savings for the other scenarios and does not reflect reality (as biosimilars currently exist).
- **Current biosimilar environment**: This scenario reflects "status quo" in the current market. Biosimilars enter the market to compete with biologics after their patents expire. We assume that after 24 months, net biosimilar prices (after rebates) paid by plan sponsors and the federal government are 30% lower than biologics, and 30% of utilization shifts to biosimilars, on average. We assume biologic manufacturers offer higher rebates to protect market share after biosimilars become available.
- **Production Plus Profit Pricing (P-quad)**: This scenario reflects the Drug Pricing Lab's proposal to base biologic drug prices on manufacturer production costs, plus a fixed profit margin after a 12-year exclusivity period. During the 12-year period, biologic manufacturers would continue to determine their own pricing for biologic products. Biosimilars would also be subject to P-quad upon market entry.
  - While prices under the P-quad proposal would be based on actual production costs and vary by drug, we assume that net biologic prices (after rebates) paid by plan sponsors and the federal government would decrease to 35% of current levels following the end of the 12-year exclusivity period. The estimated price level assumption was based on an analysis performed by the Drug Pricing Lab to estimate what biologic drug prices would look like under the P-quad proposal.[7] We selected this assumption from the upper end of the range estimated by the Drug Pricing Lab to reduce the likelihood of overestimating the financial impact of the P-quad policy proposal. We reflect this assumption as a change to plan sponsor and federal government net biologic payments, after accounting for rebates and reimbursement to other stakeholders in the industry (e.g., providers, pharmacies, intermediaries). Analyzing the appropriateness of the 35% assumption was outside of the scope of Milliman's analysis.

Figure 2 illustrates our estimated federal government savings and total savings (across plan sponsors, federal government, and beneficiaries) for the current biosimilar environment scenario and the Drug Pricing Lab's P-quad scenario from 2021 to 2025. We measure total savings by comparing total net drug spend in each scenario to the no biosimilars scenario. Net drug spend is estimated separately by market and allocated by stakeholder through cost sharing, premiums, government subsidies, and other offsets. All values are estimated net of rebates. Federal savings are based on our estimate of the government's portion of net drug spend in the Medicare Part B, Medicare Part D, Medicaid, and Individual on-exchange markets.

We assume P-quad pricing cascades through the pharmacy industry to reduce premiums, payer costs, and beneficiary cost sharing. Estimated U.S. biologic spend would increase if other stakeholders, such as providers, PBMs, wholesalers, and pharmacies, were to retain a greater portion of the P-quad price reduction. Requiring providers and other stakeholders to pass P-quad savings through to payers and beneficiaries may be needed to realize the full value of potential savings. This requirement is not a feature of the P-quad proposal.

FIGURE 2: ESTIMATED 5-YEAR FEDERAL AND TOTAL FINANCIAL SAVINGS (2021-2025) FOR CURRENT BIOSIMILAR ENVIRONMENT VS. PRODUCTION PLUS PROFIT PRICING ($ BILLIONS)



Note: Figure 2 reflects total estimated savings for plan sponsors, the federal government, and beneficiaries across the employer-sponsored, Medicare Part B, Medicare Part D, Medicaid, and individual insurance markets

This analysis assumes no behavior changes occur in the P-quad scenario. We acknowledge that in reality, stakeholders would react to this proposal in ways that could lead to materially different results. For example, manufacturers could increase biologic drug prices during the 12-year exclusivity period, biologic research and development could diminish, and beneficiaries could increase the use of biologic drugs. We also anticipate biosimilar manufacturers may opt to exit or not enter the market if this proposal were enacted. We discuss some stakeholder considerations and model the financial impact of a few potential behavior changes in the "Stakeholder Considerations" section of this report. This discussion is not intended to be exhaustive due to the uncertainty in estimating potential stakeholder reactions.

This paper also does not reflect any impact from recent final rules announced by the U.S. Department of Health and Human Services (HHS) affecting Medicare, such as the Most Favored Nations rule and the removal of safe harbor protection for manufacturer rebates under the federal anti-kickback statute. HHS cited estimates of $85 billion to $90 billion decreases in federal spending over seven years for the Most Favored Nations Rule, and a range of $100 billion decrease to $200 billion increase in federal spending over 10 years due to the manufacturer rebate rule.[8,9] These estimates reflect spending on all drugs and are not specific to biologics. We have not quantified the potential impact of these final rules on biologics.

WHAT ARE THE KEY DRIVERS OF THE IMPACT TO U.S. DRUG SPEND?

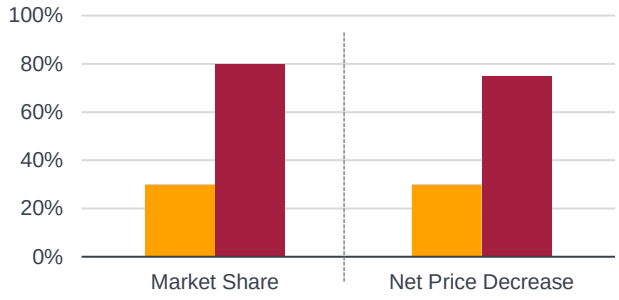
According to the Drug Pricing Lab, its P-quad proposal is intended to reduce biologic drug spend. The P-quad proposal may decrease biologic drug spend at a level similar to generic drug competition in the non-biologic drug market. Existing biosimilar competition has generated lower percentage savings than generic drugs for a variety of reasons, including drug interchangeability, number of biosimilar manufacturers, provider incentives, reimbursement levels, manufacturing complexity, and many other considerations. We provide slightly more detail in the Background section below.

Biosimilar availability, prices, and market share are key metrics and drivers of U.S. drug spend decreases from biosimilars relative to U.S. drug spend decreases from generic drugs. Figure 3 compares expected market share and net price decrease assumptions for biosimilars and generic drugs after 24 months. We discuss each key driver below:

- **Biosimilars are not available for all biologic products.** As noted above, a portion of current biologic spend is for products with expired patents, yet without biosimilars in development. The P-quad proposal would apply to all biologics, including those without biosimilars in development. This proposal would also accelerate savings for drugs with patents extended beyond a 12-year window due to additional indication approvals (e.g., Humira, Enbrel).
- **Biosimilar price savings to payers have been low relative to generics.** ASP for biosimilars is approximately 30% lower than reference biologics (pre-biosimilar launch) on average, as of July 2020.[10] Conversely, competition from traditional generic drugs has led to 55% to 95% decreases in average manufacturer price (AMP) relative to brands with two to six generic competitors.[11] Manufacturer biologic prices would be set based on production costs in the P-quad proposal, which may lead to payer price reductions closer to those due to generic drug competition.
- **Biosimilar market share has been low relative to generics.** Biosimilar market share varies considerably by product and time from launch, with 30% on average expected after 24 months.[12] In contrast, generic drugs have historically captured 70% to 90% market share within 12 to 24 months of launch.[13] The P-quad proposal would apply to both biologics (after 12-year exclusivity) and biosimilars (upon market entry), affecting the entire market.

Most recently, biosimilars have captured greater market share and driven greater savings than in prior years. The biosimilar market will continue to develop over time. Our analysis focuses on 2021 to 2025, and it is difficult to predict the long-term impact of biosimilars. The difference in savings between the Drug Pricing Lab's P-quad proposal and the current biosimilar environment may narrow over time as more biosimilars are approved and enter the market. Our estimate of five-year biosimilar savings is similar to a recent analysis from IQVIA, estimating $100 billion in savings.[14]

FIGURE 3: MARKET SHARE AND NET PRICE DECREASE FOR BIOSIMILARS AND GENERICS (RELATIVE TO REFERENCE PRODUCTS)



Biosimilars may achieve 15% to 55% market share and 15% to 45% lower prices than reference biologics after 24 months.

Generics may achieve 70% to 90% market share and 55% to 95% lower prices than reference brand products after 24 months.

Biosimilar Source: "Biosimilars in the United States 2020-2024." IQVIA. Published October 2020.

Background

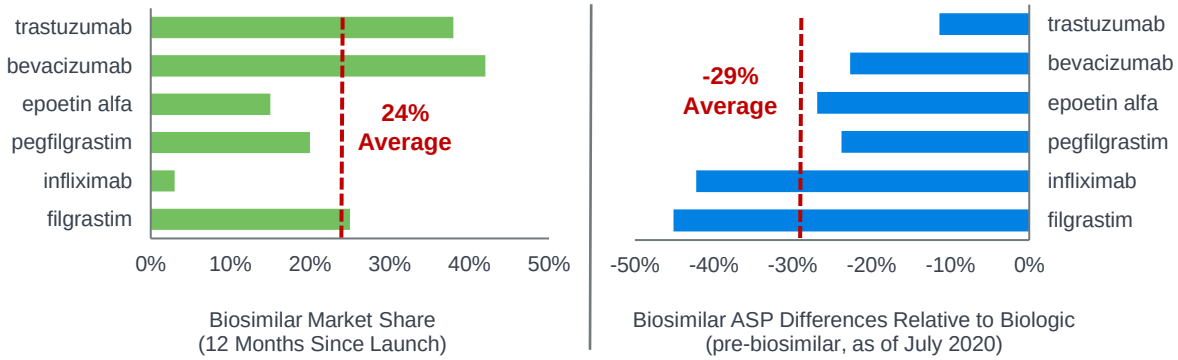
CURRENT BIOSIMILAR ENVIRONMENT

In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to create an abbreviated pathway for the FDA to approve biosimilars. As of October 14, 2020, the FDA has approved 28 biosimilars relating to 10 different reference biologics, of which 20 are available in the market to compete with eight different reference biologics.[15]

The rate of biosimilar approvals has increased in recent years. Uptake and utilization in the U.S. market, although increasing recently, has been limited. Figure 4 illustrates the market share and ASP change for existing biosimilars. We highlight a few observations below:

- **Less recent biosimilar launches primarily gained below average market share.** For example, biosimilars of Remicade (infliximab) entered the market in April 2016 and July 2017. Two years after launch, biosimilar market share was approximately 10% in the U.S. This market share has increased to 20% as of Q2 2020.[16]
- **More recent biosimilar launches primarily gained above average market share.** For example, biosimilars of Herceptin (trastuzumab) and Avastin (bevacizumab) entered the market in July 2019. The market share for these products was approximately 40% after 12 months. Several factors may drive this performance, such as competition from multiple biosimilar manufacturers and provider preference for biosimilar products. We describe more below.

FIGURE 4: U.S. MARKET SHARE AND ASP DIFFERENCES FOR EXISTING BIOSIMILARS



Source: "Biosimilars in the United States 2020-2024." IQVIA. Published October 2020

Biosimilar performance varies by product due to several key drivers. We briefly describe some of these drivers below. This list is not intended to be exhaustive, as this is not the focus of this report. There are numerous other considerations that are not contemplated here. It is also worth noting that the impact of biosimilars on biologic spend extends beyond market share and price decreases for biosimilars. For example, Remicade's ASP also decreased by approximately 30% relative to its pre-biosimilar levels, driving greater savings over time.[17]

- **Interchangeability.** The BPCIA created the ability for biosimilars to be approved as interchangeable with reference biologics. With interchangeable products, such as traditional generics, the pharmacist is allowed to substitute products without physician notification. To date, no biosimilars have been granted an interchangeable indication. The lack of interchangeability is a key contributor to biosimilar performance, as it limits the opportunity to substitute the biosimilar for the biologic.
- **Competition.** The number of competitors is often limited to a few biosimilar manufacturers, with more competitors for reference products with greater use. The number of competitors is a key driver of biosimilar performance, as greater competition may lead to greater price decreases for beneficiaries and payers.
- **Provider incentives.** Many biologics are administered by providers. Provider incentives, such as reimbursement as a percentage of list prices, can influence biosimilar performance and prescribing patterns. In addition, some providers may be able to purchase certain reference biologics at a lower price than biosimilars if eligible for the 340B Drug Pricing Program.
- **Reimbursement.** Reimbursement practices, such as up-front discounts and rebates, can influence biosimilar performance. For example, Medicare Part D plan sponsors may favor rebates over point-of-sale discounts due to the benefit design and implications for plan sponsor costs.
- **Manufacturing complexity.** Biosimilars are complex and risky to manufacture. Large up-front development costs may put upward pressure on biosimilar prices.

P-QUAD: PRODUCTION PLUS PROFIT PRICING

The Drug Pricing Lab's Production Plus Profit Pricing was first proposed by researchers Peter Bach of the Memorial Sloan Kettering Cancer Center and Mark Trusheim of the Massachusetts Institute of Technology (MIT). If implemented, P-quad would set biologic drug prices based on production costs after the expiration of a 12-year market exclusivity period approved by the FDA.[18] The price would be "cost-plus" (as described in detail below). The approach was proposed as a potential alternative to existing biosimilar competition as a means of reducing spend for biologic drugs. Biosimilars would be subject to P-quad upon entry.

In the P-quad proposal, biologic prices set by manufacturers would be tied to drug manufacturing costs, plus distribution and transaction costs, plus a defined fixed profit margin. We assume manufacturers cannot extend the 12-year period through the approval of additional indications or product modifications. We also assume this policy would apply to all biologics, including both those with and without a biosimilar in development. Figure 5 summarizes some of the details of the Drug Pricing Lab's P-quad policy proposal.

FIGURE 5: THE DRUG PRICING LAB'S P-QUAD PROPOSAL SUMMARY

1.	Biologic drug prices are based on production costs after a 12-year exclusivity period that cannot be extended.
2.	Production-based prices are tied to actual manufacturing, distribution, and transaction costs, plus a fixed profit.
3.	Biosimilars would be subject to P-quad upon market entry.
4.	This proposal would apply to all biologic and biosimilar products.

The Drug Pricing Lab's P-quad policy proposal sets biologic drug prices individually based on actual manufacturing costs. The Drug Pricing Lab developed an example of how this production-based pricing might work on its website.[19] Their estimates indicate production-based prices could range from 25% to 35% of current net price levels, after accounting for rebates.

We reviewed various external sources to benchmark against this net price assumption. One source we reviewed was cost-of-goods-sold (COGS) for biologic manufacturers to benchmark against anticipated production costs. Boston Consulting Group estimated that COGS represent 10% to 15% of revenue for biologic products.[20] This estimate is lower than the Drug Pricing Lab's estimate, which also accounts for profit margin to manufacturers and reimbursement for distribution and transaction costs. Although we did not analyze the Drug Pricing Lab's assumption, it does not contradict with our judgment based on the sources we reviewed. We do note, however, that if various stakeholders, such as providers, pharmacies, or intermediaries, were to retain a portion of the price reduction, then the beneficiary, plan sponsor, and federal government savings would be lower than those illustrated in this report (which assume a pass-through of savings from providers and other intermediaries to payers). Requiring providers and other stakeholders to pass P-quad savings through to payers and beneficiaries may be needed to realize the full value of potential savings. This requirement is not a feature of the P-quad proposal.

For ease of modeling the financial impact of this policy proposal, we assume a uniform change in net biologic prices after a 12-year window. Our baseline assumption is that P-quad prices would be 35% of current net biologic drug prices. We selected this assumption from the upper end of the range estimated by the Drug Pricing Lab to reduce the likelihood of overestimating the financial impact of the P-quad policy proposal. We also tested the impact of varying this assumption, as outlined later in this report, but analyzing the appropriateness of the 35% assumption was outside of the scope of Milliman's analysis.

This modeling approach is intended to estimate the potential average financial impact of the P-quad proposal from the perspective of plan sponsors, the federal government, and beneficiaries. Actual production-based prices would be determined directly at the drug level and would not be based on this modeling assumption. In addition, production costs for biologics may vary from biosimilars, resulting in different P-quad prices. Our analysis assumes biologic and biosimilar production costs and P-quad prices are equivalent.

Analysis and results

We developed five-year actuarial projections to estimate the potential financial impact of the Drug Pricing Lab's P-quad proposal compared to the current environment of biosimilar entry and competition. Our analysis included the major sources of healthcare financing in the United States: group (i.e., employer-sponsored), Medicare Part B, Medicare Part D, Medicaid, and on-exchange individual markets. Our analysis excludes insurance coverage through the off-exchange individual market, TRICARE and other veteran benefit programs, and other private health coverage.

Our analysis of this policy proposal considered three separate projection scenarios:

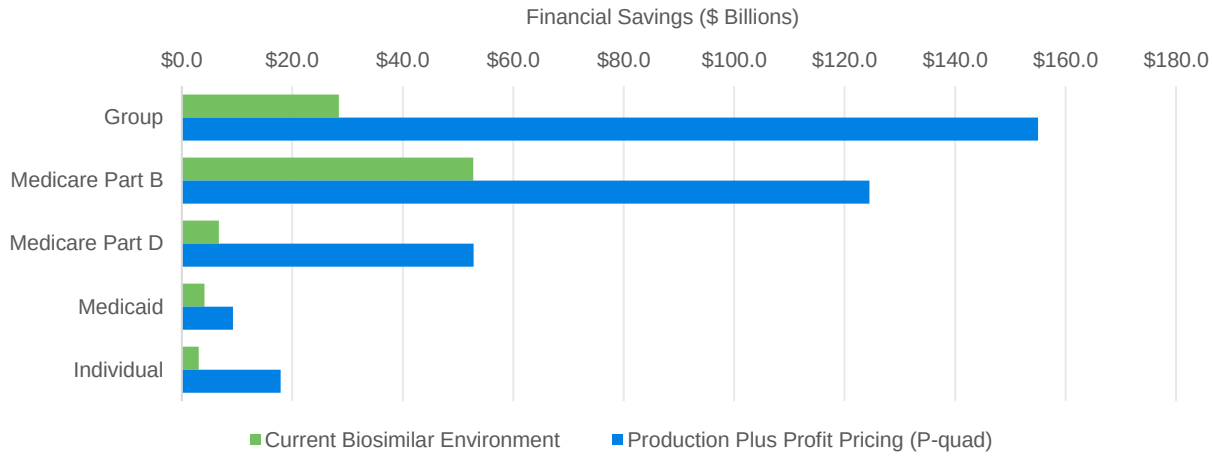
1. **No biosimilars**: As if no biosimilar competition existed and biologic prices were not regulated.
2. **Current biosimilar environment**: The status quo where biosimilars can compete with biologics after their patent expires.
3. **Production Plus Profit Pricing (P-quad)**: Biologic prices are set based on production costs after 12 years of exclusivity, and biosimilar prices are set based on production costs upon market entry. No adjustments are made for the advance research and development costs prior to production.

Figure 6 summarizes the estimated financial savings across the federal government, plan sponsors, and beneficiaries for the current biosimilar environment and P-quad scenario by market. Across all markets from 2021 to 2025, we estimate $95 billion in total savings and $45 billion in federal savings from the current biosimilar environment, and $360 billion in total savings and $145 billion in federal savings from the Drug Pricing Lab's P-quad policy proposal. Total savings in Figure 6 reflect the difference in net biologic spending between the no biosimilars scenario and both the current biosimilar environment and P-quad scenarios.

Figure 7 illustrates the estimated net biologic spending in each of the three scenarios defined above by market. Total savings are split between member cost sharing, premiums, government subsidies, and other offsets, as illustrated in the appendices. All values are estimated net of rebates. We provide more detail on the financial impact and modeling for each market in the appendices.

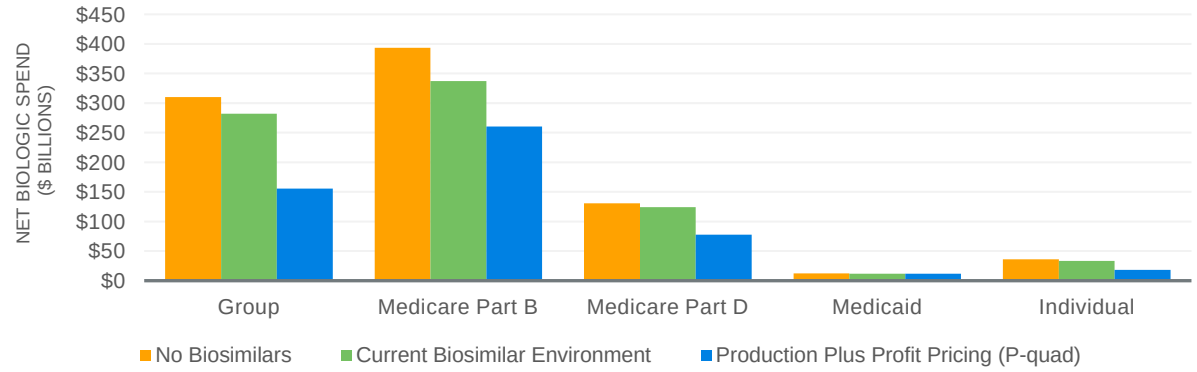
For beneficiaries dually eligible for both Medicare and Medicaid, we allocate Medicare's responsibility to Parts B and D based on claim type, and we allocate Part B cost-sharing responsibility to Medicaid. The federal savings associated with Medicaid is primarily driven by dual-eligible beneficiaries. We estimate Medicaid spending would increase for certain biologics under the P-quad proposal, due to the Medicaid Drug Rebate Program. We provide more detail on the Medicaid market in Appendix E.

FIGURE 6: ESTIMATED 5-YEAR TOTAL FINANCIAL SAVINGS BY MARKET (2021-2025) FOR CURRENT BIOSIMILAR ENVIRONMENT VS. P-QUAD PROPOSAL ($ BILLIONS)



Total savings are estimated at approximately $95 billion for the current biosimilar environment and $360 billion for the P-quad proposal from 2021 to 2025. Total savings are measured across the federal government, plan sponsors, and beneficiaries.

FIGURE 7: ESTIMATED 5-YEAR NET BIOLOGIC SPEND BY SCENARIO AND MARKET (2021-2025, $ BILLIONS)



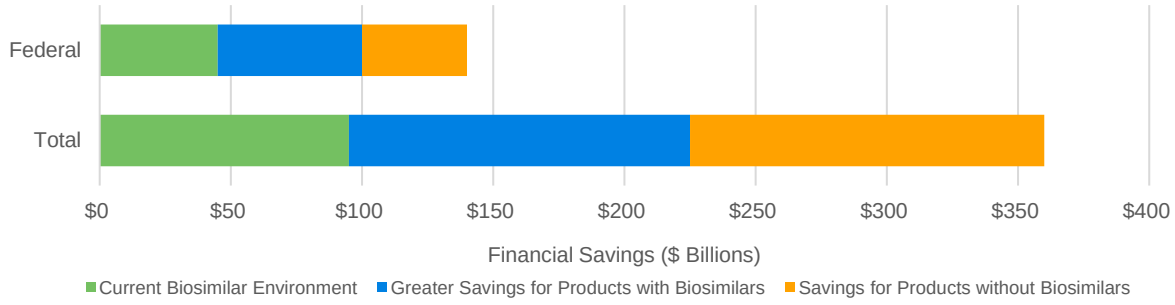
Total net biologic spend is estimated as $885 billion in the no biosimilars scenario, $790 billion in the current biosimilar environment, and $525 billion in the P-quad scenario from 2021 to 2025.

KEY DRIVERS OF INCREMENTAL SAVINGS

A few key items drive incremental savings from the Drug Pricing Lab's P-quad proposal relative to biosimilar competition. We isolate these drivers for biologics with and without biosimilar competition. Figure 8 illustrates the estimated total and federal impact attributed to each component, as described below. Federal savings are based on the federal government's estimated portion of net drug spending in the Medicare Part B, Medicare Part D, Medicaid, and individual on-exchange markets. Total savings are consistent with Figure 6 above, and reflect the impact across the federal government, plan sponsors, and beneficiaries.

1. **Greater savings for products with biosimilars**. As illustrated in Figure 3 above, expected biosimilar unit cost savings are 30% and expected market share is 30%, on average, after 24 months. With the P-quad proposal, we assume net prices decrease by 65% on average and apply to 100% of utilization. We estimate $55 billion in incremental federal savings by setting production-based prices for biologics that are facing or are expected to face biosimilar competition by 2025.
2. **Savings for products without biosimilars**. As noted in Figure 1 above, 49% of biologic spending is for products without a biosimilar in development. Appendix A summarizes 41 biologic drugs modeled in our analysis with a 12-year exclusivity window that has passed or is scheduled to pass before 2025 without any expected biosimilar competition. We estimate $40 billion in incremental federal savings through the P-quad proposal for biologics that are not expected to face biosimilar competition by 2025. These biologics do not reflect 49% of total biologic spend, but a subcategory of those biologics without a biosimilar in development with exclusivity ending by 2025.

FIGURE 8: ATTRIBUTION ANALYSIS OF ESTIMATED INCREMENTAL 5-YEAR SAVINGS (2021-2025) BETWEEN CURRENT BIOSIMILAR ENVIRONMENT AND P-QUAD PROPOSAL ($ BILLIONS)



Total savings are measured across the federal government, plan sponsors, and beneficiaries.

PREMIUM IMPACT BY MARKET

We estimate premium changes in each market for each scenario. Figure 9 illustrates the average estimated per member per month (PMPM) premiums by market from 2021 to 2025. We summarize results on each market below, with estimated premium savings relative to the no biosimilars scenario.

- **Group**: We estimate average premiums will decrease in the group market by $3.00 PMPM (-0.5%) due to biosimilar competition and would decrease by $16.25 PMPM (-2.5%) under the P-quad proposal from 2021 to 2025. Group premiums are estimated based on projected plan costs (which may be shared with beneficiaries through employee contributions), as described in Appendix B.
- **Medicare Part B**: We estimate average premium decreases in the Medicare Part B market of $3.25 PMPM (-2.0%) due to biosimilar competition and $7.75 PMPM (-4.5%) under the P-quad proposal from 2021 to 2025. We assume 25% of Part B savings in each scenario are passed on through premiums, as described in Appendix C. Illustrated premiums are gross of any subsidies for Part B beneficiaries.
- **Medicare Part D**: We estimate average premium decreases in the Medicare Part D market of $0.50 PMPM (-1.5%) due to biosimilar competition and $1.75 PMPM (-5.0%) under the P-quad proposal from 2021 to 2025. This reflects the total premium including the Low Income Premium Subsidy. More detail on these projections are provided in Appendix D.
- **Individual market**: We estimate average premium decreases in the on-exchange individual market of $4.25 PMPM (-0.5%) due to biosimilar competition and $25.75 PMPM (-4.0%) under the P-quad proposal from 2021 to 2025. Individual premiums are estimated based on projected plan costs, as described in Appendix F. Premiums reflect total premium amounts before applying Advanced Premium Tax Credits (APTCs).

FIGURE 9: ESTIMATED AVERAGE PREMIUM BY MARKET AND SCENARIO (2021-2025, PMPM)

SCENARIO	GROUP	MEDICARE PART B	MEDICARE PART D	INDIVIDUAL
No Biosimilars	$686.25	$171.50	$36.75	$659.00
Current Biosimilar Environment	$683.25	$168.25	$36.25	$654.75
Production Plus Profit Pricing (P-quad)	$670.00	$163.75	$35.00	$633.25

SENSITIVITY TESTING

We tested the impact of changing key assumptions on our total savings estimates across the federal government, plan sponsors, and beneficiaries. We summarize our testing in more detail in Appendix G. Our testing results indicated:

- **Production Plus Profit Pricing (P-quad)**: We estimate a range of total savings for this scenario of $360 billion to $410 billion. These results were based on testing P-quad net price assumptions of 25% to 35% of current levels. We used the high end of our expected range as the baseline scenario throughout this paper.
- **Current biosimilar environment**: We estimate a range of total savings from $55 billion to $135 billion. These results were based on testing biosimilar market share assumptions of 15% to 55% after two years and unit cost savings of 15% to 45%, on average. Our baseline scenario assumed both of these assumptions were 30% on average.

The biosimilar market will continue to develop over time. Our analysis focuses on the 2021-2025 period, and it is difficult to predict the long-term impact of biosimilars. The difference in savings between the Drug Pricing Lab's P-quad proposal and the current biosimilar environment may narrow over time as more biosimilars are approved and enter the market.

Stakeholder considerations

Although we did not model behavior changes in our baseline analysis, we anticipate that key stakeholders in the pharmacy supply chain would adjust their business practices in response to the Drug Pricing Lab's P-quad proposal. This section provides a brief discussion of stakeholder considerations. We also illustrate estimated impacts of certain potential stakeholder behavior changes. This discussion and analysis are not intended to be exhaustive. Stakeholder behavior changes are uncertain and difficult to predict, and this analysis is intended to illustrate some potential outcomes that may or may not materialize as illustrated. Other stakeholder considerations or behavior changes could arise that are not contemplated here.

PROVIDERS

On average, providers may purchase biologics at lower prices under the Drug Pricing Lab's P-quad proposal. Independently, providers would negotiate reimbursement levels with payers in certain markets. Through these negotiations, providers may pass through the P-quad biologic price reduction to payers or retain a portion as profit. The P-quad proposal would increase providers' profit margins if negotiated reimbursement levels do not change materially from the current environment (which is outside of the scope of the modeling in this analysis). The P-quad biologic price level assumption of 35% assumes providers pass the biologic price reduction through to payers, and payers pass the savings through to beneficiaries with lower cost sharing and premiums. We attempt to estimate the potential impact of hospitals retaining more or less margin by testing a range of P-quad price assumptions, as illustrated in Appendix G.

Under the Drug Pricing Lab's P-quad proposal, the purchase price for biologics may increase for 340B Program providers. For example, the 340B discount can approach 100% (for penny-priced drugs) in the current biosimilar environment, resulting in a purchase price that would likely be lower than the P-quad price. If payer reimbursement for 340B drugs were based on lower list prices due to P-quad, then 340B providers would need to either accept decreased profit margins or renegotiate payment terms with payers in an effort to increase reimbursement levels for certain medications. Our analysis assumes payer reimbursement to 340B providers would decrease similar to non-340B providers, regardless of changes in 340B acquisition costs. Federal programs such as 340B and the Medicaid Drug Rebate Program may require further consideration and changes if P-quad were to be implemented.

Providers may not be able to renegotiate reimbursement in certain markets (e.g., Medicare). As such, providers may be forced to adapt to lower reimbursement levels under the P-quad proposal. To compensate for this, providers may attempt to subsidize lower Medicare reimbursement by increasing reimbursement in the group market. Our analysis does not contemplate these potential changes.

MANUFACTURERS

The P-quad proposal may reduce biologic manufacturer revenue after the 12-year exclusivity period by tying prices to production costs. On average, we expect P-quad prices would be lower than price reductions or rebates offered by biologic manufacturers facing competition from biosimilars, with the exception of certain medications for Medicaid and at 340B pharmacies. This decreased revenue could lead to lower profit margins for manufacturers or reduced investment in research and development for future products, particularly biologic products. Fixed prices could also limit incentive to respond to product shortages, with prices not based on supply and demand. Biologic manufacturers may also elect to reduce or discontinue patient assistance programs for biologics subject to P-quad, which could increase beneficiary costs.

Biosimilar manufacturers would also receive lower revenue relative to the current environment. Biosimilars are complex to develop, with development costs estimated at $100 million to $250 million or more.[21] The P-quad proposal reflects production cost plus a fixed profit margin, where production costs do not explicitly include up-front research and development costs. This proposal may result in biosimilar manufacturers exiting the market or deciding not to enter the market. This would result in sunk development costs for biosimilar manufacturers that have invested in future product launches.

Biologic manufacturers could potentially respond to this proposal by increasing prices or reducing rebates prior to the end of the 12-year exclusivity period. Biologic manufacturers may also attempt to get approval for additional indications to extend patents beyond the initial 12-year exclusivity window. We illustrate the potential impact of these stakeholder responses in Figure 10 below.

INTERMEDIARIES (PBMS, WHOLESALERS, GROUP PURCHASING ORGANIZATIONS)

Intermediaries, such as PBMs, wholesalers, and group purchasing organizations (GPOs), would also be affected by the P-quad proposal. Because manufacturer prices would decrease, intermediary revenue and profit margins would also decrease if their revenue is tied to a percentage of list prices. Prescription volume could also increase, due to affordability of medications for beneficiaries. PBMs may no longer be able to negotiate rebates with biologic

manufacturers after the exclusivity period. This also could result in differences in formulary strategies if rebates are not negotiated. These entities may attempt to retain a greater "spread" of the biologic revenue to compensate for lost rebate revenue. We attempt to estimate the potential impact of intermediaries retaining more or less margin by testing a range of P-quad price assumptions in Appendix G.

PHARMACIES

Pharmacies would be able to purchase biologics at lower prices under the P-quad proposal. Pharmacy purchasing may also simplify if fewer biosimilar manufacturers enter the market. Pharmacies may not need to purchase and stock multiple biosimilars for a single reference product, and could instead only supply the reference biologic itself at comparable prices. If pharmacy revenue is tied to a percentage of drug prices, this could decrease pharmacy profit margins. Many biologics are dispensed through specialty pharmacies that provide additional services, such as member outreach and cost-sharing assistance. The fees for these services could increase to cover lost revenue from a decreased "spread" between the acquisition prices for biologics and the price charged to payers and beneficiaries. In addition, pharmacies that are eligible to purchase biologics at 340B prices could see a large increase in acquisition costs, similar to the 340B providers scenario described above. We attempt to estimate the potential impact of pharmacies retaining more or less margin by testing a range of P-quad price assumptions in Appendix G.

PLAN SPONSORS

With the P-quad proposal, we expect plan sponsors would pay less for biologic products at the point of sale. Plan sponsors affected would include federal, state, and local governments, employers, and insurance companies. Plan sponsors may experience increased prescription volume due to patient affordability, which would partially offset the reduction in biologic spending. In addition, plan sponsors could experience a reduction in medical costs due to increased medication adherence and improved health outcomes. The P-quad proposal could also change the flow of funds to plan sponsors if rebates are eliminated or reduced. Beneficiaries may see reduced cost sharing due to lower point-of-sale prices, with the potential to increase premiums due to lost rebate revenue. We expect the increase in premiums due to decreased rebates would be more than offset by the price reductions passed onto plan sponsors. Figure 10 below illustrates the estimated impact of some of these stakeholder behavior changes on plan sponsors.

BENEFICIARIES

We anticipate beneficiaries will have lower out-of-pocket costs with the P-quad proposal, through both lower cost sharing and premiums. Lower biologic drug prices may also lead to an increase in new biologic users and an increase in medication adherence, increasing biologic drug utilization. In turn, this increase in medication adherence could improve health outcomes and reduce medical costs for beneficiaries. Depending on the price of the biologic, this could also lead to fewer utilization management programs, which could increase access to medications. Figure 10 below illustrates the estimated impact of some of these potential behavior changes.

In the commercial and individual markets, beneficiary out-of-pocket costs could increase for certain members and drugs due to the prevalence of copay coupons currently in the market. Manufacturers may elect to eliminate or reduce copay coupons for products subject to P-quad, which could increase cost sharing for certain members.

POTENTIAL STAKEHOLDER BEHAVIOR CHANGES

Figure 10 below estimates the financial impact of potential stakeholder behavior changes discussed above. These P-quad scenarios measure the change in federal spending (through the Medicare, Medicaid, and individual markets) and total spending across the federal government, plan sponsors, and beneficiaries, relative to the no biosimilars scenario.

These scenarios are not intended to be exhaustive or reflect the complete range of potential financial impacts. Instead, these scenarios are intended to illustrate the relative impact of potential behavior changes on medical and pharmacy spending. While there is a great deal of uncertainty around the exact behavior changes that will occur, it is certain this policy would lead to stakeholders adjusting the way they conduct business. As such, we felt it was important to consider and model a variety of potential behavior change scenarios, as follows:

- **No stakeholder behavior changes**: This scenario reflects no stakeholder behavior changes and is consistent with the other scenarios presented throughout this report.
- **Manufacturers increase biologic prices by 25% during exclusivity and discontinue rebates**: This scenario reflects manufacturers increasing biologic drug prices by 25% during the 12-year exclusivity period, relative to existing levels, as a response to the P-quad policy proposal. This price increase would be intended to increase revenue during the exclusivity period to offset reduced revenue post-exclusivity due to the P-quad proposal. We also assume biologics no longer offer rebates during their 12-year exclusivity periods, and biologic gross cost trends increase to 10% annually. The increase in annual trends is intended to reflect the impact of new biologic medications launching at higher prices.

- **Exclusivity Period Extends from 12 Years to 15 Years**: This scenario is intended to reflect the potential impact of manufacturers extending the exclusivity period for biologic products beyond the 12-year window to 15 years. The P-quad proposal intends to disallow the practice of extending exclusivity beyond 12 years. If manufacturers were to extend patents, this may only apply to certain drugs as opposed to all drugs, but we test this across all products for this scenario.
- **Biologic utilization increases by 10% post-exclusivity**: This scenario reflects an increase in biologic utilization due to new users and increased adherence for existing users. We assume this increase occurs after the exclusivity period once the P-quad prices take effect. This scenario is intended to illustrate a potential impact, as it is uncertain how a price change of this magnitude would affect biologic use.
- **Biologic utilization increases by 10% and medical claims decrease by 0.1% post-exclusivity**: This scenario builds off the prior one and additionally assumes some savings occur on the medical benefit. These savings could be driven by increased medication adherence for existing users and improved health outcomes for new users. It is uncertain if medical savings would materialize, and it is difficult to measure or estimate the potential impact on medical claims and health outcomes. This scenario is intended to illustrate a potential impact that could deviate or not materialize as expected.

FIGURE 10: ESTIMATED 5-YEAR FEDERAL AND TOTAL FINANCIAL SAVINGS (2021-2025, $ BILLIONS) FOR P-QUAD PROPOSAL COMPARED TO NO BIOSIMILARS WITH POTENTIAL STAKEHOLDER BEHAVIOR CHANGES

		ESTIMATED SAVINGS RELATIVE TO NO BIOSIMILARS	
#	SCENARIO	FEDERAL	TOTAL
1	No stakeholder behavior changes	$140	$360
2	Manufacturers increase biologic prices by 25% during exclusivity and discontinue rebates	$110	$275
3	Exclusivity Period Extends from 12 Years to 15 Years	$120	$310
4	Biologic utilization increases by 10% post-exclusivity	$125	$335
5	Biologic utilization increases by 10% and medical claims decrease by 0.1% post-exclusivity	$130	$345

Assumptions and methodology

This analysis relied on numerous assumptions to develop our 2021-2025 projections in each market. We provide additional detail on our overall methodology and assumptions in this section. We provide more detail on our projections and each specific market in the appendices.

To develop these projections, we first identified the expected biologic patent expirations and biosimilar product launches through the end of 2025. We started with the FDA's purple book as a resource for expected biologic patent expirations. We supplemented this information with extensive market research on biologic patent expirations and expected biosimilar launches provided by the Drug Pricing Lab. We used additional internal research to validate the expected launch dates to review for reasonability. We then identified all biologic products with an expected patent expiration or market access period (biologic launch date plus 12 years) of 2025 or earlier that comprise at least 0.25% of biologic drug spending in any of the markets considered. This approach identified 66 biologic products to include in our modeling. Appendix A illustrates the biologic and biosimilar products modeled, including their assumed biosimilar launches and 12-year exclusivity end years. Our analysis does not model the pipeline of new biologics on a drug-specific basis, as they would not be subject to P-quad during the five-year projection period. We included the estimated impact of pipeline biologics through trend assumptions.

We next summarized historical utilization and gross cost by biologic drug in each market. We also summarized the historical biosimilar utilization in each market and shift from biologics to biosimilars based on biosimilar launch year. We used this data to inform biosimilar shift assumptions in the current biosimilar environment scenario. We relied on the most recent biologic definition, which changed in March 2020 to include all medications that are "humanlike" (e.g., insulins).[22] We provide more detail on the market-specific assumptions and sources of data in the appendices.

We then developed a projection model for biologic drug spending that trends utilization and cost in each market. The projection model also reflects biologic cost and utilization changes under three scenarios:

1. **No biosimilars**: Counterfactual scenario assuming biosimilars do not and never have existed.
2. **Current biosimilar environment**: Status quo scenario with current and projected biosimilar entry based on available biosimilar pipeline information and brand patent expiration dates.
3. **Production Plus Profit Pricing (P-quad)**: Policy proposal scenario where biologic drug prices are based on production costs after 12 years of exclusivity, and biosimilar prices are set upon market entry.

We estimated rebate assumptions for each market using rebate data provided by the Drug Pricing Lab. This data included separate rebate rates for the Medicaid and non-Medicaid markets. We modeled separate rebate rates in the autoimmune, insulin, and oncology classes based on spending and rebate levels. We applied a uniform rebate percentage assumption to all other biologic drugs outside of these classes.

With this information, we projected total costs by market and allocated costs to each stakeholder based on various actuarial models. Each stakeholder allocation required a different approach by market. For all markets in each baseline scenario, we ignored induced utilization associated with biologic and biosimilar prices, potential medical claim savings from improved medication adherence, and all other potential stakeholder behavior changes. We acknowledge that these stakeholder behavior changes could have a material impact on our savings estimates.

The pharmaceutical industry is complex with numerous stakeholders. In this paper, we evaluate federal government, plan sponsor, and beneficiary drug spend. We do not quantify the impact on the many additional stakeholders including providers, drug manufacturers, PBMs, other intermediaries, and non-U.S. stakeholders.

Additional methodology and assumptions for the projections and each market are outlined in the appendices:

- **Appendix A**: Biologic and Biosimilar Drugs Projection
- **Appendix B**: Group (Employer-Sponsored) Market
- **Appendix C**: Medicare Part B Market
- **Appendix D**: Medicare Part D Market
- **Appendix E**: Medicaid Market
- **Appendix F**: Individual Market
- **Appendix G**: Sensitivity Testing

Caveats and limitations

This Milliman report has been prepared for the specific purpose of summarizing the estimated savings from biosimilar competition compared to production-based pricing on U.S. biologic spending. Milliman does not intend to benefit, and assumes no duty or liability to, third parties that receive this work product. Any third-party recipient of this work product that desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its own specific needs. Any releases of this report to a third party should be in its entirety. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

MODEL AND DATA RELIANCE

Milliman has developed certain models to estimate the values included in this report. The intent of the models was to estimate net biologic drug spending and allocate costs by stakeholder. We have reviewed the models, including their inputs, calculations, and outputs, for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP).

The models rely on data and information as input to the models. We have relied upon certain data and information provided by the Drug Pricing Lab at Memorial Sloan Kettering, the Centers for Medicare and Medicaid Services (CMS), and other public sources for this purpose. We accepted these data and information without audit, but reviewed them for general reasonableness. To the extent that the data and information provided is not accurate, or is not complete, the values provided in this report may likewise be inaccurate or incomplete.

The appendices describe specific assumptions and data sources by market. Key data and information reliance includes:

- Medicare Parts A and B Claims data from the CMS Limited Data Set
- Medicaid State Drug Utilization data from the Medicaid.gov website
- Manufacturer rebate information for the Medicaid and non-Medicaid markets, provided by the Drug Pricing Lab at Memorial Sloan Kettering
- Biologic drug approval and patent expiration dates, along with biosimilar pipeline information, provided by the Drug Pricing Lab at Memorial Sloan Kettering
- Production-based prices for biologic drugs, provided by the Drug Pricing Lab at Memorial Sloan Kettering
- Total projected enrollment by market, based on information from the national health expenditure data and Kaiser Family Foundation
- Projected benefit designs and cost sharing by market, based on information from the Kaiser Family Foundation

The models, including all input, calculations, and output, may not be appropriate for any other purpose.

SOURCES OF UNCERTAINTY

The results presented herein are estimates based on carefully constructed actuarial models. Differences between our estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made for this analysis. It is certain that actual experience will not conform exactly to the assumptions used in this analysis. Actual amounts will differ from projected amounts to the extent that actual experience deviates from expected experience.

There are some major sources of uncertainty that affect our analysis. Some of these sources include:

- Recent legislation, such as the Most Favored Nations interim final rule and the removal of safe harbor protection for manufacturer rebates under the federal anti-kickback statute. Our analysis does not consider the impact of these announced final rules.
- Stakeholder behavior, such as higher drug prices, increased drug utilization, or improved medication adherence. Behavior changes could have a material impact on the estimates presented in this report, as shown in Figure 10.
- Additional complexities related to pharmaceutical competition and production-based prices. This paper does not address challenges imposed by the Drug Pricing Lab's proposal in the current pharmaceutical industry.

ACKNOWLEDGMENT OF QUALIFICATION

Kevin Pierce is an actuary at Milliman. He is a member of the American Academy of Actuaries and meets the Qualification Standards of the American Academy of Actuaries to render the actuarial opinion contained herein.

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CONTACT

Kevin Pierce
kevin.pierce@milliman.com

Dustin Pollastro
dustin.pollastro@milliman.com

Appendix A: Biologic and Biosimilar Drugs

We performed five-year projections under three separate scenarios, as introduced in the body of this paper. We highlight additional assumptions and methodology from our approach below for each scenario. Figure 11 below summarizes our average biosimilar market share assumptions by market and year since launch. Figure 12 below summarizes the modeled biologic drugs, their assumed market exclusivity years, and the anticipated biosimilar launch year.

1. **No biosimilars**: Counterfactual scenario assuming biosimilars do not and never have existed. This scenario includes a shift of existing biosimilar utilization back to the more expensive biologics. This projection provides a baseline to compare against the other scenarios to estimate savings. Our analysis does not assume any increase in biologic drug prices due to lack of biosimilar competition, with the exception of Remicade, which has had material price decreases since biosimilars have launched. However, we assume biologics do not offer additional rebates due to biosimilar competition (as described below for the current biosimilar environment scenario).

2. **Current biosimilar environment**: Status quo scenario with current and projected biosimilar entry based on available biosimilar pipeline information and biologic patent expiration dates. This projection illustrates the estimated impact due to biosimilar competition with lower prices than the original biologics. We analyzed historical biosimilar utilization data each year since the initial biosimilar launch for each market. The estimated biosimilar market share was 15% to 20% after two years based on our historical data sources. After reviewing more recent data, we decided to revise our biosimilar utilization shift and unit cost savings assumptions to target 30% market share and 30% unit cost reductions by year 2 on average, similar to IQVIA's analysis.[23]

   Figure 11 summarizes the average assumed biosimilar market share by year since launch date for our analysis. We also made targeted changes to specific classes (+15% oncology, -10% insulins) based on actual utilization in key therapeutic classes with existing biosimilars. We also assume that reference biologics offer increased rebates (at 50% of biosimilar unit cost savings) as biosimilars enter the market, and reflect this as a reduction to gross cost/ASP in the Medicare Part B market.

3. **Production Plus Profit Pricing (P-quad)**: Policy proposal scenario where biologic drug prices are based on production costs after 12 years of exclusivity and biosimilar prices are set upon market entry. We assumed net biologic drug prices would decrease by 65% after the 12-year exclusivity period and trend at general consumer price index (CPI) inflation of 2% to 3% per year thereafter. After the exclusivity period, we assume no rebates are offered for biologics and biosimilars in the non-Medicaid markets. We also assume the Medicaid inflationary rebate component approaches 0% for biologics and biosimilars. Our analysis does not reflect behavior changes that could arise from this policy, such as changes in drug utilization or changes in drug prices prior to exclusivity.

FIGURE 11: BIOSIMILAR MARKET SHARE ASSUMPTIONS FOR PROTOTYPICAL NEW BIOSIMILAR LAUNCH BY MARKET AND YEAR SINCE LAUNCH

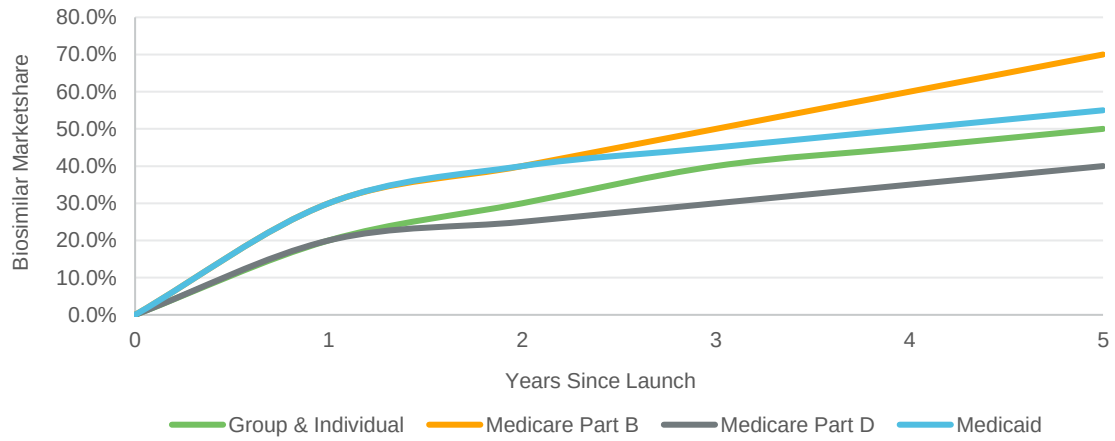


FIGURE 12: MODELED BIOLOGIC DRUGS, P-QUAD EXCLUSIVITY END YEAR, AND ANTICIPATED BIOSIMILAR LAUNCH DATES

REFERENCE BIOLOGIC	P-QUAD EXCLUSIVITY END YEAR	ANTICIPATED BIOSIMILAR LAUNCH YEAR	REFERENCE BIOLOGIC	P-QUAD EXCLUSIVITY END YEAR	ANTICIPATED BIOSIMILAR LAUNCH YEAR
Humira	pre-2021	2023	Vectibix	pre-2021	n/a
Remicade	pre-2021	2016	Aralast	pre-2021	n/a
Neulasta	pre-2021	2018	Nplate	2022	n/a
Enbrel	pre-2021	n/a	Humulin	pre-2021	n/a
Herceptin	pre-2021	2019	Gonal-f	pre-2021	n/a
Rituxan	pre-2021	2019	Actemra	2022	2022
Stelara	2023	2024	Advate	pre-2021	n/a
Avastin	pre-2021	2019	Synagis	pre-2021	n/a
Humalog	pre-2021	2018	Genotropin	pre-2021	n/a
Novolog	pre-2021	2021	Perjeta	2025	2025
Gamunex-C	pre-2021	n/a	Epogen	pre-2021	n/a
Lantus	pre-2021	2016	Tysabri	pre-2021	2022
Prolia	2025	2025	Zenpep	2023	n/a
Soliris	2021	n/a	Novoseven	pre-2021	n/a
Xolair	pre-2021	2022	Ilaris	2024	n/a
Eylea	2023	2024	Elaprase	pre-2021	n/a
Botox	pre-2021	n/a	Xgeva	2025	n/a
Pegasys	pre-2021	n/a	Aranesp	pre-2021	2024
Gammagard	pre-2021	n/a	Benlysta	2025	n/a
Levemir	pre-2021	n/a	Adcetris	2023	n/a
Avonex	pre-2021	n/a	Nutropin	pre-2021	n/a
Privigen	2022	n/a	Kogenate	pre-2021	n/a
Rebif	pre-2021	n/a	Gammagard Liquid	pre-2021	n/a
Orencia	pre-2021	2021	Prolastin-C	pre-2021	n/a
Cimzia	pre-2021	2024	Novolin	pre-2021	n/a
Lucentis	pre-2021	2021	Santyl	pre-2021	n/a
Simponi	2022	2025	Procrit	pre-2021	2018
Erbitux	pre-2021	2021	Betaseron	pre-2021	2009
Hizentra	2022	n/a	Serostim	pre-2021	n/a
Octagam	2021	n/a	Gammaplex	2025	n/a
Fabrazyme	pre-2021	n/a	Gammaked	pre-2021	n/a
Creon	2021	n/a	Cinryze	pre-2021	n/a
Pulmozyme	pre-2021	n/a	Neupogen	pre-2021	2013

Notes:

All drugs with “n/a” listed do not have an anticipated biosimilar launch by 2025.

The biologic exclusivity end year is listed as pre-2021 for all products with market start dates before 2009. Years listed as 2021-2025 are based on the market start date plus 12 years based on the FDA’s purple book.

Appendix B: Group (Employer-Sponsored) Market

The largest source of U.S. biologic spending is currently the group or employer-sponsored market. This includes medications administered by physicians or in an outpatient setting (e.g., oncology or cancer products), in addition to medications received from the pharmacy (e.g., insulin products). Funding for this market comes from member cost sharing and plan premiums, which are split between the employer and employees. Throughout this paper, amounts defined as "plan premium" in the group market include all contributions from both the employer and employee.

Biologic reimbursement rates vary widely in the group market. Physician-administered medications are typically reimbursed to hospitals based on billed charges or another reference-based price, such as ASP. Medications filled at the pharmacy are typically negotiated by PBMs and may also be based on a reference price, such as wholesale acquisition cost (WAC) or average wholesale price (AWP). PBMs may negotiate rebates with biologic and biosimilar manufacturers to favor their products (i.e., cover products on their formularies, offer lower cost sharing). Specific pharmacies, such as specialty pharmacies, may also provide additional discounts or price concessions to PBMs for driving members to their locations. PBMs and health plans may also join group purchasing organizations (GPOs) to leverage their volume to negotiate more favorable terms or rebates for biologic drugs. The rebate levels for plan sponsors can vary considerably based on their PBM contracts and group size. However, these post-point-of-sale discounts can contribute meaningfully to reducing overall pharmacy spending. Our analysis does not reflect plan sponsors offering point-of-sale rebates, which have been growing in popularity in the group market. We reflect all rebates in this market as post-point-of-sale.

Figure 13 illustrates estimated group market spend from 2021 to 2025 for each scenario. *We estimate $28 billion in savings from the current biosimilar environment and $155 billion in savings from the Drug Pricing Lab's P-quad policy proposal from 2021 to 2025 in the group market.* These savings are split between plan premiums, which are paid by employers and employees, and member cost sharing.

We projected biologic and total healthcare spend for 2021 to 2025 as described in the Assumptions and Methodology section above. We calibrated a claim probability distribution (CPD) from Milliman's Health Cost Guidelines™ (HCGs) to project biologic and non-biologic spend for each scenario. We then applied an assumed benefit design to allocate costs between member cost sharing and plan premiums in each scenario. We also relied on the following assumptions:

- **Data source**: We relied on Milliman's 2018 Consolidated Health Cost Guidelines Sources Database (CHSD) to summarize historical utilization and cost for all biologics in the group market.
- **Trends**: We relied on the projected National Health Expenditures (NHE) for the group market to calibrate total healthcare claim trends.[24] Biologic utilization and unit cost trends were selected as 3% and 7%, respectively, based on historical biologic trend information and Milliman's research on future brand and specialty drug trends.
- **Enrollment**: We relied on projected enrollment for the group market based on data from the Kaiser Family Foundation.[25] This source estimates that approximately 158 million individuals had employer-sponsored coverage in 2019. We relied on NHE projection data to estimate the year-over-year change in employer-sponsored coverage enrollment from 2021 to 2025.[26]
- **Benefit design**: We relied on a benefit design with a deductible of $1,500, coinsurance of 20%, and a maximum out-of-pocket (MOOP) of $4,000, informed by research from the Kaiser Family Foundation's Employer Health Benefits Survey.[27] We trended this benefit by 3% annually to assume member cost sharing grows as total healthcare cost grows.

FIGURE 13: ESTIMATED 5-YEAR TOTAL HEALTHCARE SPENDING BY COMPONENT IN GROUP MARKET (2021-2025) FOR CURRENT BIOSIMILAR ENVIRONMENT VS. PRODUCTION PLUS PROFIT PRICING ($ BILLIONS)

CATEGORY	2021	2022	2023	2024	2025	TOTAL
SPENDING						
No Biosimilars						
Member Cost Sharing	$265.8	$274.0	$283.1	$292.4	$303.7	$1,419.0
Plan Premium	$1,183.5	$1,234.2	$1,288.8	$1,344.7	$1,411.9	$6,463.1
Total Spending	$1,449.3	$1,508.2	$1,571.9	$1,637.1	$1,715.6	$7,882.1
Current Biosimilar Environment						
Member Cost Sharing	$265.8	$274.0	$283.1	$292.4	$303.6	$1,418.9
Plan Premium	$1,180.5	$1,230.3	$1,283.5	$1,337.5	$1,403.0	$6,434.8
Total Spending	$1,446.3	$1,504.3	$1,566.6	$1,629.9	$1,706.6	$7,853.7
Production Plus Profit Pricing (P-quad)						
Member Cost Sharing	$265.5	$273.7	$282.7	$292.0	$303.2	$1,417.1
Plan Premium	$1,159.7	$1,207.5	$1,258.3	$1,310.5	$1,374.0	$6,310.0
Total Spending	$1,425.2	$1,481.2	$1,541.0	$1,602.5	$1,677.2	$7,727.1
SAVINGS						
Current Biosimilar Environment						
Member Cost Sharing	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Plan Premium	$3.0	$3.9	$5.3	$7.2	$8.9	$28.3
Total Savings	$3.0	$3.9	$5.3	$7.2	$9.0	$28.4
Production Plus Profit Pricing (P-quad)						
Member Cost Sharing	$0.3	$0.3	$0.4	$0.4	$0.5	$1.9
Plan Premium	$23.8	$26.7	$30.5	$34.2	$37.9	$153.1
Total Savings	$24.1	$27.0	$30.9	$34.6	$38.4	$155.0
Incremental Savings From P-quad in Excess of Biosimilar Savings						
Member Cost Sharing	$0.3	$0.3	$0.4	$0.4	$0.4	$1.8
Plan Premium	$20.8	$22.8	$25.2	$27.0	$29.0	$124.8
Total Additional Savings	$21.1	$23.1	$25.6	$27.4	$29.4	$126.6

Note: Dollar amounts reflect total healthcare spending, net of rebates, including spending for medical services.

Appendix C: Medicare Part B Market

Medicare Part B covers outpatient hospital and physician-administered medications for Medicare beneficiaries. Medicare Part B covers most of the biosimilars that are available in the United States today. Funding for this market comes from beneficiary cost sharing, beneficiary premiums, and the federal government. Medicare Part B spending is split between traditional Medicare fee-for-service (FFS) and Medicare Advantage (MA). In addition, some Medicare beneficiaries pay for Medicare Supplement insurance (Medigap), which provides coverage for some cost-sharing requirements under traditional Medicare FFS. Our modeling considered each line of business separately to estimate the impact on Medicare beneficiaries and key stakeholders differently. We also carved out cost sharing and premiums for dual-eligible beneficiaries to allocate to the Medicaid market, as Medicaid is responsible for these expenses.

Medicare reimburses providers at a fixed amount, published quarterly, for Medicare Part B drugs. The reimbursement for physician-administered medications is based on average sales price (ASP). ASP is defined as the average sales per unit of a drug to all U.S. purchasers within a quarter, net of all price concessions and rebates (excluding those from the Medicaid Drug Rebate Program).[28] Medicare reimbursement to non-340B providers is equal to 106% of ASP for biologic products (an amount reduced by budget sequestration to 104.3%). Medicare reimburses providers for biosimilars using the biosimilar's ASP, plus the mark-up associated with the original biologic (i.e., 6% of the biologic's ASP). This reimbursement keeps the providers' margin neutral between biosimilars and biologics, removing an incentive for providers to administer more expensive biologics. Medicare Advantage plans may negotiate supplemental rebates, but these rebates may be limited for Part B drugs as ASP is calculated net of rebates.

Figure 14 illustrates the five-year projections of Medicare Part B spend by stakeholder under each scenario**.** *We estimate $37 billion in federal savings from the current biosimilar environment and $88 billion in federal savings from the Drug Pricing Lab's P-quad policy proposal from 2021 to 2025 in the Medicare Part B market.* Total savings are split between beneficiary cost sharing, beneficiary premiums, and federal payments. These estimates do not reflect any impact from the Most Favored Nations interim final rule announced by HHS on November 20, 2020.[29]

We projected biologic and total Part B spend for 2021 to 2025 as described in the Assumptions and Methodology section above. We calibrated an actuarial cost model to our gross cost projections to allocate the projected costs between stakeholders. We applied the Medicare Part B plan design to separate CPDs for biologic and non-biologic users. We applied separate plan designs (described below) for Medicare FFS, Medicare Advantage, and Medicare Supplement insurance to develop the costs by stakeholder. We illustrate the aggregate results of our analysis across these products. We also relied on the following assumptions:

- **Data source**: We relied on CMS's 2018 Limited Data Set to summarize historical utilization and cost for biologic and non-biologic users in the Medicare Part B market.[30] We summarized all costs associated with these separate members, not just biologic drug spending.
- **Trends and enrollment**: We relied on projected Medicare Part B expenditures and enrollment from the 2020 Medicare Trustees report to calibrate claim trends. Biologic trends are assumed to trend at the same rate as physician-administered drugs from the Trustees report. This source implies a growth from 59 million Part B beneficiaries in 2021 to 65 million in 2025. This enrollment includes dual-eligible beneficiaries.
- **Biosimilar cost**: The final biosimilar cost assumptions for the Medicare Part B market are slightly different from the values noted in the Assumptions and Methodology section above. We assume providers receive the same dollar profit margin for the biosimilar as the biologic, based on current regulations. We also incorporate an adjustment for 340B reimbursement based on the actual distribution of claims at 340B versus non-340B hospitals.
- **Premiums and government payments**: We assume the following by Medicare segment:
  - *Part B premium*: We used the expected Part B premiums through 2025 from the 2020 Medicare Trustees report. We also assumed the government would share 25% of Part B savings from each scenario with beneficiaries through member premiums. The premium applies to all members (FFS, Medigap, and MA).
  - *Medigap*: We assumed member premiums reflect the reduced plan liability due to biosimilar competition and the P-quad proposal.
  - *MA*: We estimated the average MA premium for each projection year using historical premium information. We included an average Part B buy-down offered by some MA plans as an offset to the MA premium.
  - *Government payments*: We assumed the government's MA payment rates are adjusted to account for savings from the P-quad proposal and biosimilar competition.
- **Benefit design**: We assume the following by Medicare segment. Please note that across all markets, cost sharing may be covered by Medicaid or employers, and does not exclusively reflect member out-of-pocket costs.
  - *FFS*: We applied the average FFS cost sharing with parameters trended as in the 2020 Medicare Trustees report. We assumed no cost sharing for home health and hospice services and 20% coinsurance on all remaining Part B services.

- *Medigap*: There is a variety of standardized Medigap plans, with each plan type covering different aspects of the standard FFS cost sharing. We used historical enrollment data from the America's Health Insurance Plans (AHIP) State of Medigap 2019 report, with adjustments for plans no longer sold, to create the average cost sharing for Medigap members.
- *MA*: We analyzed publicly available plan designs for 2016 through 2020 by service category. We created an average 2020 benefit design, then trended this for each program year using historical trends. Most MA plans do not have deductibles, and therefore we assumed a $0 deductible for all projection years.

FIGURE 14: ESTIMATED 5-YEAR TOTAL HEALTHCARE SPENDING BY COMPONENT IN MEDICARE PART B MARKET FOR CURRENT BIOSIMILAR ENVIRONMENT VS. PRODUCTION PLUS PROFIT PRICING (2021-2025, $ BILLIONS)

CATEGORY	2021	2022	2023	2024	2025	TOTAL
SPENDING						
No Biosimilars						
Federal	$564.0	$594.1	$633.9	$670.3	$708.0	$3,170.3
Member	$204.3	$215.4	$229.6	$244.4	$260.7	$1,154.4
Total Spending	$768.3	$809.5	$863.5	$914.7	$968.7	$4,324.7
Current Biosimilar Environment						
Federal	$560.8	$588.7	$626.8	$661.1	$695.6	$3,133.0
Member	$202.9	$213.2	$226.6	$240.6	$255.6	$1,138.9
Total Spending	$763.7	$801.9	$853.4	$901.7	$951.2	$4,271.9
Production Plus Profit Pricing (P-quad)						
Federal	$552.9	$581.0	$616.0	$650.1	$682.5	$3,082.5
Member	$199.6	$209.9	$222.1	$236.0	$250.1	$1,117.7
Total Spending	$752.5	$790.9	$838.1	$886.1	$932.6	$4,200.2
SAVINGS						
Current Biosimilar Environment						
Federal	$3.2	$5.4	$7.1	$9.2	$12.4	$37.3
Member	$1.4	$2.2	$3.0	$3.8	$5.1	$15.5
Total Savings	$4.6	$7.6	$10.1	$13.0	$17.5	$52.8
Production Plus Profit Pricing (P-quad)						
Federal	$11.1	$13.1	$17.9	$20.2	$25.5	$87.8
Member	$4.7	$5.5	$7.5	$8.4	$10.6	$36.7
Total Savings	$15.8	$18.6	$25.4	$28.6	$36.1	$124.5
Incremental Savings From P-quad in Excess of Biosimilar Savings						
Federal	$7.9	$7.7	$10.8	$11.0	$13.1	$50.5
Member	$3.3	$3.3	$4.5	$4.6	$5.5	$21.2
Total Additional Savings	$11.2	$11.0	$15.3	$15.6	$18.6	$71.7

Note: Dollar amounts reflect total healthcare spending, net of rebates, including spending for medical services.

Appendix D: Medicare Part D Market

Medicare Part D covers medications for beneficiaries purchased at pharmacies. Limited biosimilar competition exists in the current market, but biosimilars are expected to launch for some blockbuster products over the next five years (e.g., Humira). Part D costs are split between the following stakeholders:

- **Federal government**: Through federal reinsurance, direct subsidy, and low-income subsidies.
- **Medicare beneficiary**: Through member cost sharing and premiums.
- **Pharmaceutical manufacturers**: Through the Coverage Gap Discount Program (CGDP). Figure 15 only reflects the impact to manufacturers through CGDP payments and does not reflect the impact of revenue reductions for pharmaceutical manufacturers through biosimilar competition or the P-quad proposal.

Similar to the pharmacy benefit in the group market, Medicare Part D reimbursement is typically negotiated by PBMs on behalf of plan sponsors. Although Medicare Part D is funded by the federal government, private insurance companies facilitate the benefit for beneficiaries. Reimbursement for biologic drugs are typically based on a reference-based price, such as AWP or WAC. Manufacturer and pharmacy rebates can be significant in the Medicare Part D market, with the Medicare Trustees estimating total rebates will amount to nearly 30% of total Part D costs in 2021.[31] The Medicare Part D program structure may incentivize plan sponsors to favor higher list prices and higher-rebate products, as they may lead to lower costs for the plan. This dynamic may create roadblocks for biosimilars to gain traction in this market, as illustrated by some of the insulin products that have launched to date.[32]

Figure 15 illustrates the estimated Medicare Part D market spend for 2021 to 2025 for each scenario. We estimate $5 billion in federal savings from the current biosimilar environment and $33 billion in federal savings from the Drug Pricing Lab's P-quad policy proposal from 2021 to 2025 in the Part D market. This analysis does not reflect any policy changes, such as the final rule announcing removal of safe harbor protection for manufacturer rebates under the federal anti-kickback statute. This analysis also reflects the impact to the individual Part D market, including standalone Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MAPD) plans. Our analysis excludes the group Part D market, such as Employer Group Waiver Plans (EGWPs).

We projected biologic and total Part D spend for 2021 to 2025 as described in the Assumptions and Methodology section above. We calibrated an actuarial cost model to our gross cost projections and applied the Medicare Part D defined standard plan design to allocate costs by stakeholder. We then computed the estimated subsidies and cost sharing for each year based on the statutorily defined formulas. The federal government stakeholder estimates may include some costs covered by state governments for dual-eligible beneficiaries. We also relied on the following assumptions:

- **Data source**: We relied on Milliman's 2019 Part D Consolidated Database (PDCD) to summarize historical utilization and cost for all biologics in the Medicare Part D market.
- **Trends and enrollment**: We relied on the projected Medicare Part D expenditures and enrollment from the 2020 Medicare Trustees report to calibrate total claim trends. Biologics are assumed to trend at the same rate as group products (3% utilization trend and 7% unit cost trend). This source implies a growth from 42 million beneficiaries in 2021 to 47 million in 2025.

FIGURE 15: ESTIMATED 5-YEAR TOTAL NET SPENDING BY COMPONENT IN MEDICARE PART D MARKET FOR CURRENT BIOSIMILAR ENVIRONMENT VS. PRODUCTION PLUS PROFIT PRICING (2021-2025, $ BILLIONS)

CATEGORY	2021	2022	2023	2024	2025	TOTAL
SPENDING						
No Biosimilars						
Federal	$85.2	$92.5	$99.6	$107.2	$113.4	$497.9
Member	$35.0	$38.2	$41.3	$44.5	$47.4	$206.4
Pharma (CGDP)	$9.1	$10.0	$10.7	$11.4	$11.9	$53.1
Total Spending	$129.3	$140.7	$151.6	$163.1	$172.7	$757.4
Current Biosimilar Environment						
Federal	$84.9	$92.0	$98.7	$105.9	$111.7	$493.2
Member	$34.9	$38.0	$41.1	$44.2	$47.0	$205.2
Pharma (CGDP)	$9.0	$9.9	$10.5	$11.2	$11.7	$52.3
Total Spending	$128.8	$139.9	$150.3	$161.3	$170.4	$750.7
Production Plus Profit Pricing (P-quad)						
Federal	$80.7	$87.1	$93.1	$99.7	$104.8	$465.4
Member	$33.5	$36.4	$39.2	$42.1	$44.6	$195.8
Pharma (CGDP)	$7.6	$8.3	$8.8	$9.2	$9.5	$43.4
Total Spending	$121.8	$131.8	$141.1	$151.0	$158.9	$704.6
SAVINGS						
Current Biosimilar Environment						
Federal	$0.3	$0.5	$0.9	$1.3	$1.7	$4.7
Member	$0.1	$0.2	$0.2	$0.3	$0.4	$1.2
Pharma (CGDP)	$0.1	$0.1	$0.2	$0.2	$0.2	$0.8
Total Savings	$0.5	$0.8	$1.3	$1.8	$2.3	$6.7
Production Plus Profit Pricing (P-quad)						
Federal	$4.5	$5.4	$6.5	$7.5	$8.6	$32.5
Member	$1.5	$1.8	$2.1	$2.4	$2.8	$10.6
Pharma (CGDP)	$1.5	$1.7	$1.9	$2.2	$2.4	$9.7
Total Savings	$7.5	$8.9	$10.5	$12.1	$13.8	$52.8
Incremental Savings From P-quad in Excess of Biosimilar Savings						
Federal	$4.2	$4.9	$5.6	$6.2	$6.9	$27.8
Member	$1.4	$1.6	$1.9	$2.1	$2.4	$9.4
Pharma (CGDP)	$1.4	$1.6	$1.7	$2.0	$2.2	$8.9
Total Additional Savings	$7.0	$8.1	$9.2	$10.3	$11.5	$46.1

Note: Dollar amounts reflect total Medicare Part D spending, net of rebates.

Appendix E: Medicaid Market

Medicaid covers biologic medications administered both in-person by physicians and filled at the pharmacy for children and adults with income below a certain threshold. Beneficiaries generally pay no cost sharing or a low, fixed copay for biologics, leaving the majority of the costs to be covered by federal and state governments.[33] The amount covered by the federal government varies by state and is defined based on the published Federal Medical Assistance Percentage (FMAP).

Medicaid drug pricing varies by state, with reimbursement commonly based on actual acquisition cost (AAC) or national average drug acquisition costs (NADAC), plus a fixed dispensing fee. Medicaid also receives significant rebates through the Medicaid Drug Rebate Program, which applies nationwide. In 2018, the rebates in the Medicaid market accounted for approximately 60% of gross drug costs.[34] Medicaid rebates can equal 100% of the average manufacturer price (AMP) for a specific drug, but are capped not to exceed 100% under current regulations. We considered the following two sources of rebates from the Medicaid Drug Rebate Program for this analysis:

- **Standard rebate for innovator brand products**: Manufacturers are required to pay a rebate that is the greatest of 23.1% of AMP or the difference between AMP and the "best price" offered by a manufacturer to another stakeholder for the prescription drug.
- **Inflationary rebate**: Manufacturers are also required to pay a price protection rebate for drugs with price increases that exceed standard inflation. The inflation rebate is calculated as the difference between the drug's current quarter AMP and the drug's launch date AMP trended at a standard Consumer Price Index for All Urban Customers (CPI-U) rate of inflation.

Figure 16 illustrates the estimated Medicaid market spend for 2021 to 2025 for each scenario. *We estimate $3 billion in federal savings from the current biosimilar environment and $6 billion in federal savings from the Drug Pricing Lab's P-quad policy proposal from 2021 to 2025 in the Medicaid market.* We also expect that Medicaid could pay more for specific drugs under both scenarios if the reference biologic had significant price increases over time, due to the inflationary rebate component. The majority of the federal savings are driven by Medicaid coverage of Medicare Part B cost sharing for dual-eligible beneficiaries.

We projected biologic and total Medicaid spend for 2021 to 2025 as described in the Assumptions and Methodology section above. To allocate the projected costs between stakeholders, we relied on the FMAP to allocate government costs between state and federal budgets. We assumed that cost sharing for biologics is limited (under 0.1% of total costs), and the majority of costs will be borne by the government. We computed a weighted average FMAP assumption based on historical biologic spending by state and calendar year (CY) 2021 FMAP by state, and applied that percentage to projected savings for each scenario to allocate costs by stakeholder.[35] We made adjustments for the Children's Health Insurance Program (CHIP) population and the Medicaid expansion population to account for the enhanced FMAP associated with both, and our resulting FMAP assumption allocated 65% of Medicaid costs and savings to the federal government. We also relied on the following assumptions:

- **Data source**: We relied on the 2019 Medicaid State Drug Utilization Data to summarize historical utilization and cost for all biologics in the Medicaid market.[36]
- **Trends and enrollment**: We relied on the projected Medicaid expenditures from the Medicaid NHE projections to calibrate total claim trends. Biologic utilization is assumed to remain flat and unit costs are assumed to trend at 7.5% annually. The biologic trends were based on a review of historical Medicaid biologic utilization and unit cost changes over the past five years.
- **Enrollment**: We relied on the data from the U.S. Census Bureau for 2019 enrollment. This source estimates that approximately 53 million individuals were enrolled in Medicaid in 2019, excluding dual-eligible members.[37] We relied on enrollment trends from the NHE data to project Medicaid enrollment to 2025. This analysis does not reflect any change in Medicaid enrollment due to unemployment changes because of the COVID-19 pandemic.
- **Dual-eligibles**: We excluded dual-eligible beneficiaries from our Medicaid analysis, as they were included in our Medicare Part B and Medicare Part D analyses. However, we allocated Medicare Part B cost sharing and premiums to Medicaid spending for dual-eligible beneficiaries. Our analysis does not reflect any transfers from state budgets to Medicare Part D for dual-eligible members. We assume approximately 11 million to 12 million beneficiaries are dually eligible for Medicaid and Medicare, based on information from the U.S. Census Bureau.[38]

FIGURE 16: ESTIMATED 5-YEAR HEALTHCARE SPENDING BY COMPONENT IN MEDICAID MARKET (2021-2025) FOR CURRENT BIOSIMILAR ENVIRONMENT VS. PRODUCTION PLUS PROFIT PRICING ($ BILLIONS)

CATEGORY	2021	2022	2023	2024	2025	TOTAL
SPENDING						
No Biosimilars						
State	$178.1	$187.9	$198.2	$207.7	$219.6	$991.5
Federal	$330.7	$348.9	$368.0	$385.7	$407.8	$1,841.1
Total Spending	$508.8	$536.8	$566.2	$593.4	$627.4	$2,832.6
Current Biosimilar Environment						
State	$177.9	$187.7	$197.9	$207.3	$219.2	$990.0
Federal	$330.4	$348.5	$367.5	$385.1	$407.0	$1,838.5
Total Spending	$508.3	$536.2	$565.4	$592.4	$626.2	$2,828.5
Production Plus Profit Pricing (P-quad)						
State	$177.6	$187.4	$197.5	$206.9	$218.7	$988.1
Federal	$329.9	$348.0	$366.8	$384.4	$406.1	$1,835.2
Total Spending	$507.5	$535.4	$564.3	$591.3	$624.8	$2,823.3
SAVINGS						
Current Biosimilar Environment						
State	$0.2	$0.2	$0.3	$0.4	$0.4	$1.5
Federal	$0.3	$0.4	$0.5	$0.6	$0.8	$2.6
Total Savings	$0.5	$0.6	$0.8	$1.0	$1.2	$4.1
Production Plus Profit Pricing (P-quad)						
State	$0.5	$0.5	$0.7	$0.8	$0.9	$3.4
Federal	$0.8	$0.9	$1.2	$1.3	$1.7	$5.9
Total Savings	$1.3	$1.4	$1.9	$2.1	$2.6	$9.3
Incremental Savings From P-quad in Excess of Biosimilar Savings						
State	$0.3	$0.3	$0.4	$0.4	$0.5	$1.9
Federal	$0.5	$0.5	$0.7	$0.7	$0.9	$3.3
Total Additional Savings	$0.8	$0.8	$1.1	$1.1	$1.4	$5.2

Note: Dollar amounts reflect total healthcare spending, net of rebates, including spending for medical services.

Appendix F: Individual Market

Individuals who do not receive health insurance coverage from one of the other markets described above may elect to purchase a plan from the individual market. The individual market is primarily purchased online through exchange platforms where consumers can select between different health insurance options. The individual market covers both physician-administered drugs and prescription drugs filled at the pharmacy. The individual market is highly subsidized, with funding coming from the federal government through Advanced Premium Tax Credits (APTCs), member premiums, and member cost sharing.

Similar to the group market, pharmacy benefit biologic drug reimbursement in the individual market is typically negotiated by PBMs on behalf of plan sponsors. Reimbursement for biologic drugs is typically based on a reference-based price, such as AWP or WAC. PBMs typically negotiate rebates with biologic manufacturers to favor their products (i.e., cover products on their formularies, offer lower cost sharing). Physician-administered medications may be reimbursed to hospitals based on billed charges or another reference-based price, such as ASP. Our analysis does not reflect carriers offering point-of-sale rebates, which have been growing in popularity. We reflect all rebates in this market as post-point-of-sale.

Figure 17 illustrates estimated individual market spend from 2021 to 2025 for each scenario. *We estimate $3 billion in federal savings from the current biosimilar environment and $15 billion in federal savings from the Drug Pricing Lab's P-quad policy proposal from 2021 to 2025 in the individual market.* Total savings are split between federal APTCs, member premiums, and member cost sharing.

We projected biologic and total healthcare spend for 2021 to 2025 as described in the Assumptions and Methodology section above. We calibrated a claim probability distribution (CPD) from Milliman's Health Cost Guidelines (HCGs) to projected biologic and non-biologic spend for each scenario. We then applied assumed benefit designs to allocate costs between member cost sharing and plan premiums in each scenario. We estimated federal APTCs based on the projected silver plan premiums as our "benchmark" plan. We assumed 87% of the individual on-exchange market receives APTCs based on 2020 open enrollment data.[39] We also assumed for the population receiving APTCs, 85% of premiums are subsidized on average by the federal government.[40] We used this information to estimate the baseline APTCs.

For the Drug Pricing Lab's P-quad policy proposal, we assumed that 100% of premium savings for subsidized members would be passed through to APTCs, with the remaining 13% of members seeing decreases in member premium. APTCs are calculated based on the difference between a benchmark plan's premium (i.e., premium for the second-lowest-premium silver plan) and a percentage of an individual's income (varied based on the income level).The average subsidized member's premium obligation is approximately $120 PMPM compared to a total premium of approximately $660 PMPM in our baseline projections. We project relatively small premium changes ($25 PMPM) due to this policy proposal in comparison. As such, we do not expect the savings from the policy proposal are large enough to trigger a decrease in a subsidized member's premium obligation, even for the least subsidized individual (with income at 400% of the federal poverty level).

We also relied on the following assumptions:

- **Data source**: We relied on Milliman's 2018 Consolidated Health Cost Guidelines Sources Database (CHSD) to summarize historical utilization and cost for all biologics in the individual market.
- **Trends**: We relied on the same healthcare trends as the group market based on National Health Expenditures (NHE) projections.[41] Biologic utilization and unit cost trends were selected as 3% and 7%, respectively, based on historical biologic trend information and Milliman's research on future brand and specialty drug trends.
- **Enrollment**: The on-exchange individual market currently covers approximately 11.4 million people.[42] We assume market enrollment changes at the same rate as the group market. This assumes no major legislative changes occur that would affect individual market enrollment. This projection only reflects the on-exchange individual market enrollment, and does not reflect the off-exchange population. People covered under veterans benefits, such as TRICARE, and other private insurance coverage are excluded from these estimates.
- **Metallic levels**: We project cost sharing separately under representative bronze, silver, and gold plan designs. We also modeled separate plan designs for the 73, 87, and 94 silver cost-sharing reduction (CSR) variants. Plan designs were based on average deductibles from 2020 and were selected to target actuarial values (AVs) corresponding to each metallic level.[43] We assumed a metallic-level distribution of approximately 33% bronze, 7% standard silver, 8% gold, and 52% CSR plans based on 2020 open enrollment data.[44]

FIGURE 17: ESTIMATED 5-YEAR TOTAL HEALTHCARE SPENDING BY COMPONENT IN INDIVIDUAL MARKET (2021-2025) FOR CURRENT BIOSIMILAR ENVIRONMENT VS. PRODUCTION PLUS PROFIT PRICING ($ BILLIONS)

CATEGORY	2021	2022	2023	2024	2025	TOTAL
SPENDING						
No Biosimilars						
Federal APTCs	$66.7	$69.7	$72.8	$76.1	$79.8	$365.1
Member Cost Sharing	$18.7	$19.3	$19.9	$20.6	$21.5	$100.0
Member Premium	$14.9	$15.6	$16.4	$17.2	$18.2	$82.3
Total Spending	$100.3	$104.6	$109.1	$113.9	$119.5	$547.4
Current Biosimilar Environment						
Federal APTCs	$66.4	$69.3	$72.3	$75.4	$78.9	$362.3
Member Cost Sharing	$18.7	$19.3	$19.9	$20.6	$21.5	$100.0
Member Premium	$14.9	$15.6	$16.4	$17.1	$18.1	$82.1
Total Spending	$100.0	$104.2	$108.6	$113.1	$118.5	$544.4
Production Plus Profit Pricing (P-quad)						
Federal APTCs	$64.3	$67.0	$69.8	$72.7	$76.0	$349.8
Member Cost Sharing	$18.6	$19.2	$19.8	$20.5	$21.4	$99.5
Member Premium	$14.6	$15.2	$16.0	$16.7	$17.7	$80.2
Total Spending	$97.5	$101.4	$105.6	$109.9	$115.1	$529.5
SAVINGS						
Current Biosimilar Environment						
Federal APTCs	$0.3	$0.4	$0.5	$0.7	$0.9	$2.8
Member Cost Sharing	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Member Premium	$0.0	$0.0	$0.0	$0.1	$0.1	$0.2
Total Savings	$0.3	$0.4	$0.5	$0.8	$1.0	$3.0
Production Plus Profit Pricing (P-quad)						
Federal APTCs	$2.4	$2.7	$3.0	$3.4	$3.8	$15.3
Member Cost Sharing	$0.1	$0.1	$0.1	$0.1	$0.1	$0.5
Member Premium	$0.3	$0.4	$0.4	$0.5	$0.5	$2.1
Total Savings	$2.8	$3.2	$3.5	$4.0	$4.4	$17.9
Incremental Savings From P-quad in Excess of Biosimilar Savings						
Federal APTCs	$2.1	$2.3	$2.5	$2.7	$2.9	$12.5
Member Cost Sharing	$0.1	$0.1	$0.1	$0.1	$0.1	$0.5
Member Premium	$0.3	$0.4	$0.4	$0.4	$0.4	$1.9
Total Additional Savings	$2.5	$2.8	$3.0	$3.2	$3.4	$14.9

Note: Dollar amounts reflect total healthcare spending, net of rebates, including spending for medical services.

Appendix G: Sensitivity Testing

We sensitivity-tested some of the key assumptions underlying this analysis to assess a potential range of impacts. This section highlights some of the key assumptions we tested for this analysis. Figure 20 below also visualizes these results.

BIOLOGIC PRICE REDUCTION

There is a range of potential price reductions associated with this policy proposal. Figure 18 illustrates the impact of varying the price reduction assumption for the P-quad proposal. We illustrate three scenarios of price reduction assumptions ranging from 65% to 75%. We used the low end of our estimated range as the baseline throughout this paper. We estimate five-year federal savings would be $20 billion greater, at $160 billion, with an estimated 75% price reduction compared to the estimated 65% price reduction underlying our analysis.

FIGURE 18: ESTIMATED 5-YEAR FEDERAL AND TOTAL FINANCIAL SAVINGS BY MARKET (2021-2025) FOR P-QUAD PROPOSAL AT VARYING PRICE REDUCTION ASSUMPTIONS ($ BILLIONS)

	65% PRICE REDUCTION		70% PRICE REDUCTION		75% PRICE REDUCTION	
Market	**Total**	**Federal**	**Total**	**Federal**	**Total**	**Federal**
Group	$155.0	$0.0	$165.0	$0.0	$175.0	$0.0
Medicare Part B	$124.5	$87.7	$132.5	$93.3	$140.5	$99.0
Medicare Part D	$52.8	$32.7	$56.3	$35.3	$59.8	$38.0
Medicaid	$9.3	$6.0	$10.6	$6.9	$12.0	$7.8
Individual	$17.9	$15.2	$19.1	$16.2	$20.2	$17.2
Total	$359.5	$141.6	$383.5	$151.7	$407.6	$161.9

BIOSIMILAR ASSUMPTIONS

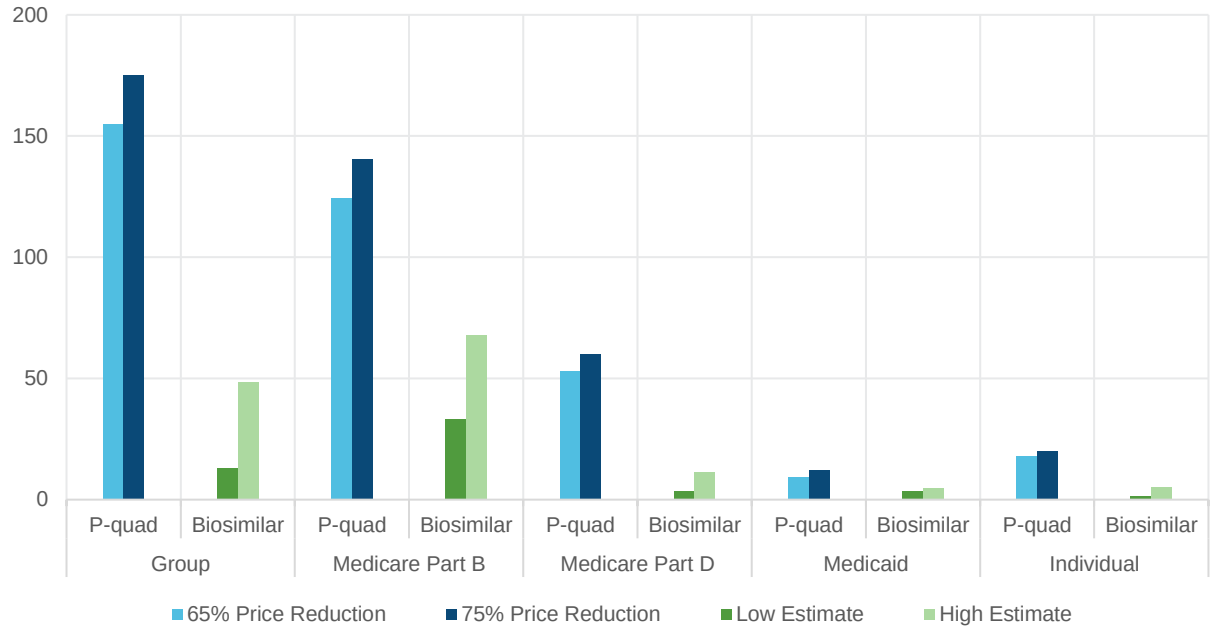
We also tested the current biosimilar environment assumptions to illustrate the financial impact of additional biosimilar utilization shift and unit cost savings. Figure 19 illustrates the estimated total and federal savings impact of biosimilar competition under three scenarios described below. We ultimately used the mid scenario for our analysis, reflecting biosimilar utilization shift and cost savings considerably higher than the historical values we reviewed.

- **Low scenario**: This scenario reflects historical biosimilar utilization and unit cost savings achieved through 2019. This scenario reflects an approximately 10% to 30% utilization shift after two years, grading up to a 25% to 60% utilization shift after five years. We estimate $55 billion in total savings and $25 billion in federal savings from 2021 to 2025 in the low scenario.
- **Mid scenario**: This scenario reflects a 15% increase in the biosimilar utilization shift and a 15% increase in biosimilar unit cost savings compared to the low scenario. We estimate $95 billion in total savings and $45 billion in federal savings from 2021 to 2025 in the mid scenario.
- **High scenario**: This scenario reflects a 30% increase in the biosimilar utilization shift and a 30% increase in biosimilar unit cost savings compared to the low scenario. We estimate $135 billion in total savings and $65 billion in federal savings from 2021 to 2025 in the high scenario.

FIGURE 19: ESTIMATED 5-YEAR FEDERAL AND TOTAL FINANCIAL SAVINGS BY MARKET (2021-2025) FOR CURRENT BIOSIMILAR ENVIRONMENT FOR LOW, MID, AND HIGH SCENARIOS ($ BILLIONS)

	LOW SCENARIO		MID SCENARIO		HIGH SCENARIO	
Market	**Total**	**Federal**	**Total**	**Federal**	**Total**	**Federal**
Group	$12.9	$0.0	$28.4	$0.0	$48.3	$0.0
Medicare Part B	$33.2	$19.7	$52.8	$37.4	$67.7	$50.8
Medicare Part D	$3.4	$2.6	$6.7	$4.8	$11.2	$7.5
Medicaid	$3.4	$2.2	$4.1	$2.7	$4.7	$3.1
Individual	$1.4	$1.2	$3.0	$2.6	$5.1	$4.4
Total	$54.3	$25.7	$95.1	$47.4	$137.1	$65.8

FIGURE 20: ESTIMATED RANGE OF 5-YEAR TOTAL HEALTHCARE SAVINGS BY MARKET (2021-2025) FOR CURRENT BIOSIMILAR ENVIRONMENT AND P-QUAD PROPOSAL ($ BILLIONS)



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