MILLIMAN REPORT

Estimated cost of potential “frozen formulary” legislation

Fully insured commercial payer impact, 2021-2025

Commissioned by Pharmaceutical Care Management Association

January 25, 2021

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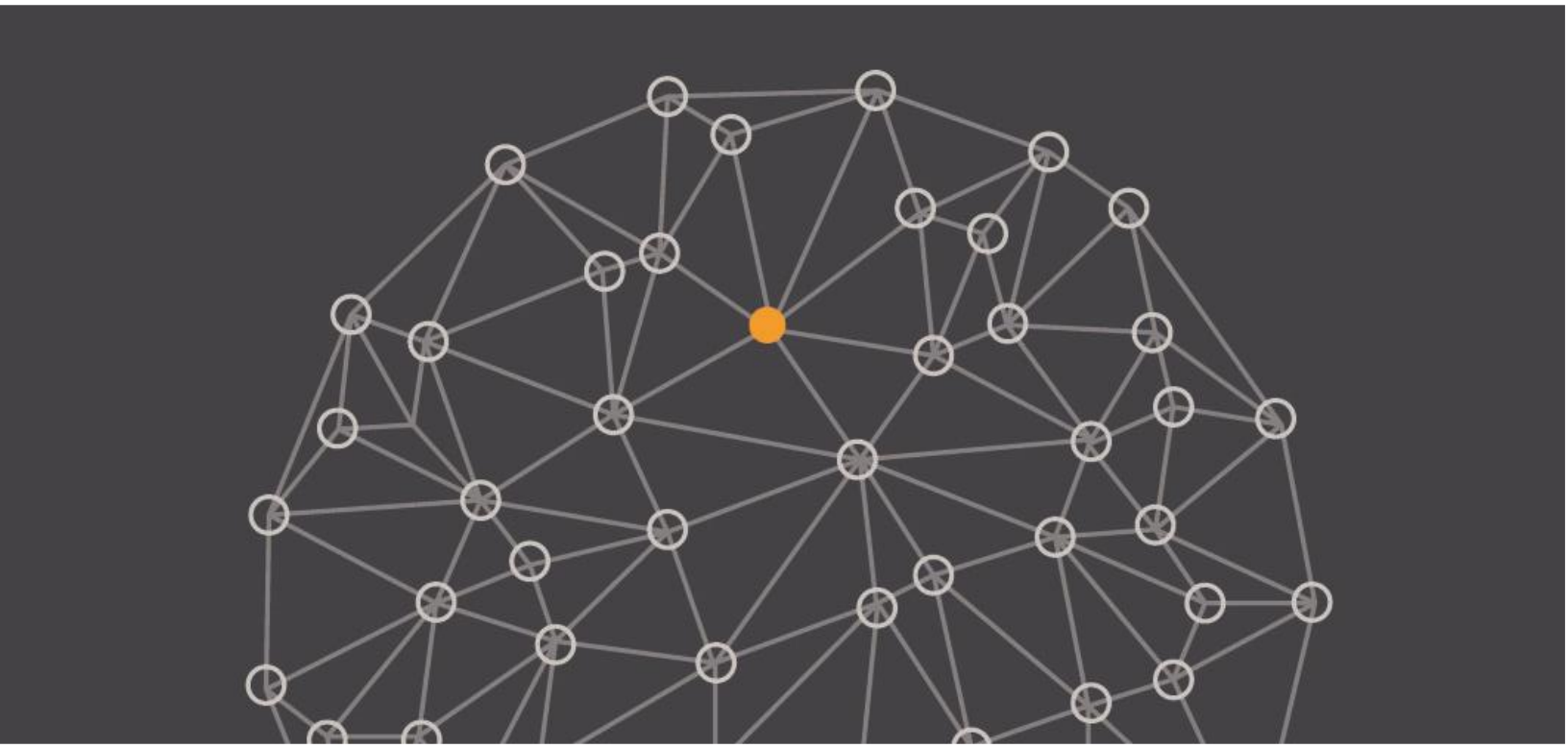

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Executive Summary

The Pharmaceutical Care Management Association (PCMA) engaged Milliman to assess the financial impact of potential "frozen formulary" legislation on fully insured commercial health insurance market payer costs. "Frozen formulary" legislation refers to regulations proposed by state legislators that would prohibit a pharmacy benefit manager (PBM) or health plan from making certain changes to a prescription formulary midyear that would negatively affect members of the plan. The Centers for Medicare and Medicaid Services (CMS) refers to these types of changes as "negative formulary changes".[1] Definitions of negative formulary changes in the fully insured commercial market vary by state, but often include moving a drug to a tier with higher cost sharing, removing a drug from the formulary, or adding more restrictive utilization management (UM) requirements.[2,3] The proposed "frozen formulary" legislation does not restrict "positive formulary changes" that would increase medication access or decrease out-of-pocket costs for members.

We estimate the proposed "frozen formulary" legislation would increase payer prescription drug costs in the fully insured commercial health insurance market by approximately $4.3 billion to $7.1 billion over five years from 2021 through 2025 on a nationwide basis. "Cost" in this report refers to the portion of prescription drug claims covered by payers, and reflects outpatient pharmacy claims, net of rebates and member cost sharing. A "payer" is defined as the entity that ultimately pays for the prescription; in the fully insured commercial health insurance market, payers are typically fully insured plan sponsors. PBMs may facilitate payments on plan sponsors' behalf. We do not model the impact on self-insured plans, as they may not be subject to state-specific legislation.

INTRODUCTION, SCOPE, AND PURPOSE

In the current fully insured commercial health insurance market, payers are typically able to change their formularies or lists of covered prescription medications and the associated requirements for accessing prescription drug benefits at any point throughout the plan year. Under current practice, negative formulary changes may occur at any time with advance notice. Several state legislatures are considering "frozen formulary" legislation, which would restrict the ability of payers to make negative formulary changes during the plan year. For example, payers may not be allowed to remove medications from a formulary or move medications to higher cost-sharing tiers under the proposed "frozen formulary" legislation. Payers would be able to make these changes after the end of the plan year, along with other annual updates. Proposed "frozen formulary" legislation varies by state.[4]

Proposed "frozen formulary" legislation may minimize member disruption by maintaining medication coverage and member cost sharing throughout the plan year. For example, under current regulations, members taking an existing brand medication could face an increase in cost sharing midyear when a new product launches. Under the proposed "frozen formulary" legislation, members would be guaranteed that the cost sharing of their medications would not change during the year. However, the legislation may also result in new medications not being covered on formulary upon launch, which would limit member access to these new medications.

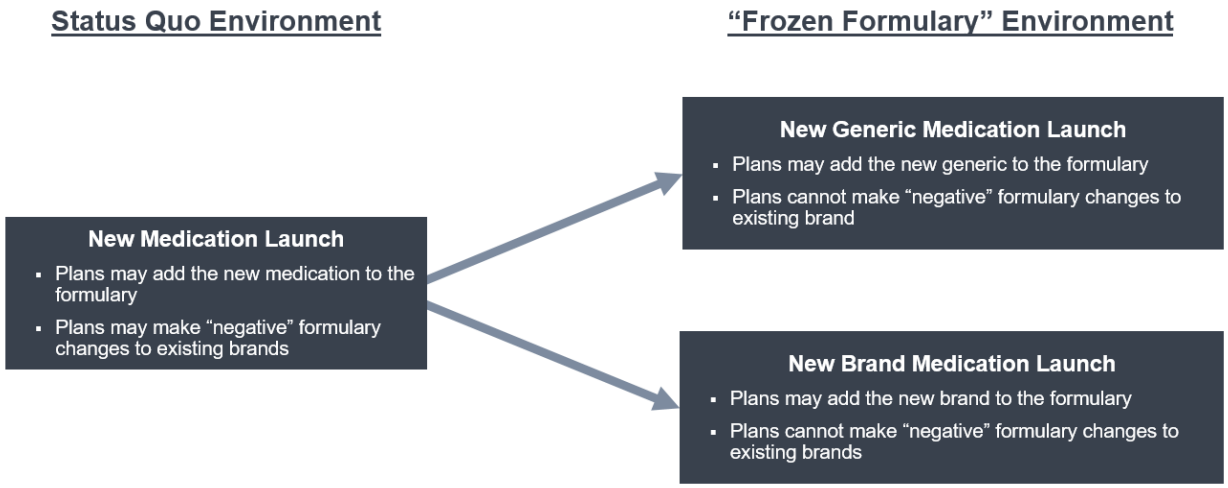
This proposed legislation may also limit the flexibility of payers to update the formulary midyear. Payers frequently modify formularies, with both positive and negative formulary changes, as they evaluate medication safety, efficacy, and cost. Medication price inflation and newly approved medications, including generic launches, are examples of market events reviewed by a Pharmacy and Therapeutics (P&T) committee that may lead to formulary changes throughout the year. By limiting formulary control through proposed "frozen formulary" legislation, payers would need to delay negative formulary changes until the end of the year, which may result in higher prescription spending. For example, payers may not be able to optimally manage pharmacy costs by applying UM to promote lower-cost medications or leverage newly available brands to negotiate for higher rebates on an existing brand with a pharmaceutical manufacturer. If this flexibility does not exist, it may increase member cost sharing and premiums.

[1] CMS (January 15, 2016). Medicare Prescription Drug Benefit Manual, Chapter 6. Retrieved January 5, 2021, from https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
[2] The New York Senate. Senate Bill S2849A. Retrieved January 5, 2021, from https://www.nysenate.gov/legislation/bills/2019/s2849
[3] Aimed Alliance. Nonmedical switching – enacted laws. Retrieved January 5, 2020 from: https://aimedalliance.org/nonmedical-switching-enacted-laws/
[4] Reger, Alex (January 6, 2020). Prescription Drug Formulary Changes. Retrieved January 5, 2021, from https://cga.ct.gov/2019/rpt/pdf/2019-R-0310.pdf

This report outlines our analysis of the estimated financial impact of this potential legislation for the fully insured commercial health insurance market. We considered two key provisions that could trigger a negative midyear formulary change and estimate the financial impact. Each of the provisions may result in a wide range of potential financial and operational disruption. Potential "frozen formulary" legislation may not be limited to the two provisions below. We describe each provision below, and additionally highlight the considered provisions in Figure 1.

1. **New generic medication launch:** When a new generic medication becomes commercially available, payers are currently able to remove the existing associated brand(s) from the formulary, add a step therapy, or up-tier the multisource brand product. With proposed "frozen formulary" legislation, this provision restricts the payer's ability to make negative changes to the multisource brand product when the chemically equivalent generic becomes available during the plan year.
2. **New brand medication launch:** When a new brand medication becomes commercially available, payers are currently able to up-tier, add UM, or remove existing associated brand(s) from the formulary to incentivize use of the new brand medication during the plan year. With proposed "frozen formulary" legislation, this provision restricts the payer's ability to make negative formulary changes to the existing brand products.

FIGURE 1: DIAGRAM OF CONSIDERED PROVISIONS UNDER PROPOSED "FROZEN FORMULARY" LEGISLATION



Note: Definitions of negative formulary changes in the fully insured commercial market vary by state, but often include moving a drug to a tier with higher cost sharing, removing a drug from the formulary, or adding more restrictive utilization management (UM) requirements.[5,6]

SUMMARY OF FINDINGS

If both provisions above were implemented nationally, we estimate payer prescription drug costs in the fully insured commercial health insurance market could increase by approximately $0.6 billion to $1.1 billion for an estimated 86 million members in 2021, increasing to $1.2 billion to $1.8 billion in 2025. These estimates represent a $4.3 billion to $7.1 billion increase, or 1.1% to 1.8%, in five-year aggregate prescription drug costs for fully insured commercial payers for 2021 through 2025 relative to the current environment. Assuming prescription drug expenditures represent 20% of total medical and pharmacy spending,[7] this represents a 0.2% to 0.4% increase in aggregate payer medical and prescription drug costs. Figure 2 illustrates a range of financial outcomes due to the potential "frozen formulary" legislation.

[5] The New York Senate. Senate Bill S2849A. Retrieved January 5, 2020 from: https://www.nysenate.gov/legislation/bills/2019/s2849
[6] Aimed Alliance. Nonmedical switching – enacted laws. Retrieved January 5, 2020 from: https://aimedalliance.org/nonmedical-switching-enacted-laws
[7] Girod, C., Houchens, P., Liner, D. et al. (May 2020). 2020 Milliman Medical Index. Milliman Research Report. Retrieved January 5, 2021, from https://us.milliman.com/-/media/milliman/pdfs/articles/2020-milliman-medical-index.ashx

FIGURE 2: ESTIMATED PAYER COST OF PROPOSED "FROZEN FORMULARY" LEGISLATION ($ MILLIONS)

	2021	2022	2023	2024	2025	2021-2025
Low	$580	$710	$850	$990	$1,150	$4,280
Mid	$790	$930	$1,080	$1,240	$1,430	$5,470
High	$1,070	$1,230	$1,400	$1,580	$1,790	$7,070

These estimates reflect the change in prescription drug cost solely attributable to payers in the fully insured commercial market. Estimates for 2021 through 2025 reflect anticipated fully insured commercial health insurance market enrollment and constant prescription drug expenditure trend. The low to high estimates reflect a range of assumed brand patent expirations and new-to-market medications. Figure 3 illustrates a range of 2021 financial outcomes for each provision:

1. **New generic medication launch**. We estimate this change could increase payer prescription drug costs by $540 million to $680 million in 2021 and by $1.1 billion to $1.3 billion in 2025.
2. **New brand medication launch**. We estimate this change could increase payer prescription drug costs by $40 million to $390 million in 2021 and by $50 million to $460 million in 2025.

FIGURE 3: ESTIMATED PAYER COST OF PROPOSED "FROZEN FORMULARY" LEGISLATION IN 2021 ($ MILLIONS)

Provision	Low	Mid	High
New Generic Medication Launch	$540	$610	$680
New Brand Medication Launch	$40	$180	$390
Total	$580	$790	$1,070

Appendix I illustrates the projected financial impact from Figure 2 above by state. Current and proposed legislation varies by state; our analysis estimates the impact if all states were to implement the proposed legislation for both of the provisions defined above. Appendix II shows the estimates from Figure 2 above on a per member per year (PMPY) basis. We estimate that the provisions noted above could increase payer prescription drug costs in the fully insured commercial health insurance market by approximately $7.00 to $13.00 PMPY in 2021, increasing to $13.75 to $21.25 PMPY in 2025. These estimates represent a 0.9% to 1.6% increase in prescription drug costs for fully insured commercial payers in 2021, primarily driven by the new generic medication launch provision.

Cost estimates for future years are primarily driven by unit cost and utilization trend and reflect the impact of new brand and generic pipeline medications. Expected savings due to new generic medications is based on historical experience. The future drug pipeline will emerge differently from what is anticipated. The illustrated range of financial outcomes is intended to reflect this future uncertainty.

Findings

We estimate the proposed "frozen formulary" legislation could increase payer prescription drug costs in the fully insured commercial health insurance market by approximately $0.6 billion to $1.1 billion in 2021, increasing to $1.1 billion to $1.8 billion by 2025 on a nationwide basis. The following sections provide detail on each modeled provision.

NEW GENERIC MEDICATION LAUNCH

Generic medications are lower-cost, chemically equivalent alternatives to brand medications and can be substituted by a pharmacist without physician approval. For example, pregbalin is the generic version of the brand medication Lyrica. Although the active ingredient is identical, the brand name medication (Lyrica) typically has a higher ingredient cost compared to its generic equivalent. Brand manufacturers facing patent expiration may provide significant rebates to payers as channel incentives, but generic price reductions offered by competing generic manufacturers typically outweigh the value of these rebates over time. Brand manufacturers may also stop providing rebates once the generic loses exclusivity. In addition to having a lower net cost, generic products generally have lower member cost sharing than the respective brand products.

When a generic medication is approved and launched into the market, payers typically make formulary changes that incentivize members to switch to the less expensive generic medication. For example, payers may up-tier the respective brand medication, add step therapy, or remove the brand medication from the prescription formulary. The formulary changes are typically effective immediately without advanced member notification. Members are also informed at the point of sale and generic substitution occurs by the dispensing pharmacist.

This provision of the proposed "frozen formulary" legislation would prohibit midyear negative formulary changes to the brand product intended to incentivize using the generic product. As a result, payers will be required to cover the brand product at the same member cost-sharing level for the entire year regardless of whether a generic medication launches during the plan year. This situation would typically result in higher costs for payers and members because we expect fewer members would switch from the brand medication to the generic medication for the remainder of the plan year compared to the current environment. Other factors, such as the prevalence of copay coupons for brand medications in the fully insured market, could also influence greater use of brand medications in a "frozen formulary" environment.

Figure 4 illustrates the estimated additional prescription drug cost due to this provision to fully insured commercial health payers. The estimates in Figure 4 reflect an increase in brand utilization as a result of potential "frozen formulary" legislation and do not reflect potential changes in associated rebate contracts. While expected generic launch savings underlies these estimates for each year, the values in Figure 4 are not estimates of actual generic launch savings.

FIGURE 4: ESTIMATED PAYER COST OF "NEW GENERIC MEDICATION LAUNCH" PROVISION ($ MILLIONS)

	2021	2022	2023	2024	2025	2021-2025
Low	$540	$670	$810	$950	$1,100	$4,070
Mid	$610	$750	$890	$1,040	$1,220	$4,510
High	$680	$830	$980	$1,140	$1,330	$4,960

We do not attempt to estimate the impact of the generic pipeline in each specific year. Rather, these estimates are based on the estimated generic launch impact for 2021, adjusting for prescription drug utilization and inflation trends. These estimates do not reflect the impact of future biosimilar competition, such as for biosimilars of Humira, which are expected to become commercially available over this time horizon and could have a material financial impact on payer and member costs. The range of cost estimates each year reflects uncertainty of future brand patent expirations.

NEW BRAND MEDICATION LAUNCH

When a new brand medication receives approval and is released in the market, the brand manufacturer may offer rebates in exchange for formulary placement. In therapeutic classes with competitive brand and/or generic medications available, payers may choose not to add a new brand medication until favorable pricing terms, or rebates, are

negotiated. In addition, payers can use the newly approved competitor as leverage to renegotiate the pricing for existing brands in the therapeutic class. Payers may up-tier an existing brand or add UM to minimize use while the drug is on formulary. Flexibility to implement formulary changes midyear enables payers to maintain or improve pricing terms with brand manufacturers, regardless of whether they ultimately make any formulary changes.

This provision of proposed "frozen formulary" legislation would restrict the ability of payers to add UM, up-tier, or remove from the formulary an existing brand medication, if a competing brand were launched midyear, as leverage for contract negotiations. In the current environment, pricing terms for brand manufacturers may be based on limiting competition from existing brands as well as new brands. If the new brand is added, it may result in less favorable pricing terms for the existing formulary brand products. If the new brand is not added, pricing terms may be maintained, but access to the new medication may be delayed until the end of the year. Payers may also attempt to proactively negotiate pricing terms prior to the new brand launching. This proactive strategy may have limited effectiveness as the approved indication and price of the new brand is essential to the prescription formulary decision and is not known until the new brand is approved and launched. If a payer were not able to make negative formulary changes when a new brand product launches, brand manufacturers would be able to maintain formulary status throughout the year and would have less incentive to renegotiate more favorable contract terms with the payer.

In evaluating this provision, we considered separate situations for the new brand medication, focusing on the first situation below in our analysis:

1. **New lower-price brand**: We expect payers are more likely to make negative formulary changes to existing products when a new brand launches at a lower price. These negative changes would incentivize the use of the lower-priced brand medication, which may lead to a cost reduction for payers. For example, Mavyret launched in August 2017 to treat hepatitis C at a list price of $26,400 per course, approximately 65% lower than the list price of medications Harvoni and Epclusa.[8] Commercial payers may have added Mavyret to their formularies in 2017 and removed or up-tiered coverage for Harvoni and Epclusa to incentivize the use of Mavyret. Rebates may also have been renegotiated due to the availability of additional hepatitis C treatments. Under the proposed "frozen formulary" legislation, payers could choose to cover Mavyret, but would not have been able to change coverage for Harvoni and Epclusa in 2017. This scenario is representative of our estimates in Figure 5.
2. **New more clinically effective brand with higher price**: We expect payers are less likely to make negative formulary changes if a new brand has a higher price, which could occur when a new product is more clinically effective. Incentivizing the use of a more clinically effective brand with a higher price may lead to an increase in payer costs. For example, Shingrix launched in October 2017 as a vaccine to prevent shingles with a higher efficacy rate and higher price than the incumbent, Zostavax.[9] Commercial payers may have added Shingrix to their 2017 formularies, but many payers may have maintained existing coverage of Zostavax. We expect favoring Shingrix would increase payer costs, as members would be taking the more expensive medication. Under the proposed "frozen formulary" legislation, payers would not have had the flexibility to remove Zostavax from the formulary or increase cost sharing midyear to improve their negotiating position with the manufacturer of Shingrix. However, we expect this situation would occur infrequently in the current environment, with payers adding Shingrix but also maintaining coverage for Zostavax. As such, we do not explicitly model the impact of this scenario in Figure 5, as we do not expect proposed "frozen formulary" legislation would have a material impact on payer costs in this situation.

Figure 5 illustrates the estimated additional prescription drug cost to fully insured commercial payers due to this "frozen formulary" provision. These values represent the opportunity cost of not being able to effectively renegotiate rebate contracts when a new brand medication launches at a lower price than associated brand medications in the class. The increase in rebates due to a new brand launch varies widely by therapeutic class and amounts are typically confidential. We also acknowledge that differences in gross cost and member cost sharing would also affect the estimated impact of this provision. For these reasons, we illustrate a range of potential outcomes to capture these dynamics.

[8] Liu, Angus (May 18, 2020). Special Reports: 1. Mavyret. Fierce Pharma. Retrieved January 5, 2021, from https://www.fiercepharma.com/special-report/mavyret-top-10-drug-launches-since-2017

[9] Liu, Angus (May 18, 2020). Special Reports: 4. Shingrix. Fierce Pharma. Retrieved January 5, 2021, from https://www.fiercepharma.com/special-report/shingrix-top-10-drug-launches-since-2017

FIGURE 5: ESTIMATED PAYER COST OF "NEW BRAND MEDICATION LAUNCH" PROVISION ($ MILLIONS)

	2021	2022	2023	2024	2025	2021-2025
Low	$40	$40	$40	$40	$50	$210
Mid	$180	$180	$190	$200	$210	$960
High	$390	$400	$420	$440	$460	$2,110

Cost estimates for future years are primarily driven by unit cost and utilization trend. The overall assumed brand trends reflect the impact of new brand pipeline medications. Drug-specific cost and utilization impacts are not explicitly modeled in our analysis.

STATE-SPECIFIC ESTIMATES

Several state legislatures have considered various forms of "frozen formulary" legislation.[10,11] PCMA requested that we illustrate the estimated additional cost to fully insured commercial payers due to potential "frozen formulary" legislation at both the nationwide and state levels. While we illustrate the potential impact for all states, not all states are currently considering this type of legislation. Appendix I illustrates the projected financial impact by state.

The state-level estimates do not reflect current or potential future state-specific medication coverage requirements. Rather, we allocate the estimated nationwide cost impact based on state-specific prescription medication expenditures and fully insured commercial health plan enrollment. We assume the distribution of prescription medication expenditures by state remains constant from 2021 to 2025. Nationwide enrollment trends from 2021 to 2025 are consistent with CMS National Health Expenditure enrollment trends and do not vary by state. The Methodology section below provides detail on the state-specific enrollment and prescription drug expenditure assumptions underlying the illustrative state allocation.

OTHER CONSIDERATIONS

"Lower member cost" provision

Some proposed "frozen formulary" legislation would not permit negative midyear formulary changes, unless the new medication results in lower member cost sharing. That is, negative midyear changes would be permitted if they result in lower member cost (same as in the current market), but would not be permitted if they result in higher member cost.

We expect new generic medications, which are generally lower-price and covered on lower cost-sharing tiers compared to brand medications, would result in lower member cost and not be affected by this provision.

We expect new brand medications could be affected by this provision if they are covered at the same or higher member cost compared to existing brands. A new brand could be covered at a higher member cost if it launches at a higher price; as described above, we expect payers are unlikely to make negative formulary changes in this situation. A new brand could be covered at the same member cost if the benefit design includes fixed copays and the new brand is covered on the same copay tier as the existing brands. As such, we expect this provision would reflect a proportion of the payer cost impact illustrated in Figure 5 above for the "new brand medication launch" provision, as it would only apply to the proportion of plans that have a copay benefit design. For brand drugs launching at a lower price, the lower-priced brand could lead to lower member costs due to the prevalence of deductibles, coinsurance, and out-of-pocket maximums in the commercial market, mitigating the potential effect of this provision.

Biosimilars and biologics

Proposed "frozen formulary" legislation could limit the ability of payers to make negative formulary changes to an existing biologic or biosimilar product when a new biosimilar enters the market midyear. Biosimilars are highly similar

[10] Reger, Alex, Prescription Drug Formulary Changes, op cit.
[11] Reger, Alex (September 11, 2017). Prescription Drug Formulary Legislation in Select States. Retrieved January 5, 2021. from https://www.cga.ct.gov/2017/rpt/2017-R-0203.htm

to and have no meaningful clinical differences relative to their reference biologic counterparts. Biosimilars introduce competition for biologic products that may allow payers to negotiate more favorable pricing for classes of drugs.

Over the next five years, certain biologics are set to have their patents expire, such as Humira. These upcoming biologic patent expirations and any associated biosimilar launches may introduce an opportunity for payers to renegotiate pricing terms if payers have the flexibility to adapt to these market changes. That opportunity would be delayed until the end of the plan year under proposed "frozen formulary" legislation. Payers would have the ability to add biosimilars to the formulary, but would not be able to make negative changes to the existing biosimilars as a result of the proposed legislation. As of January 2021, most available biosimilars are covered under the medical benefit and would not be affected by this proposed legislation. The impact of the future biosimilar pipeline is highly uncertain and difficult to estimate with such limited existing experience on the pharmacy benefit.

In addition, the Biologics Price Competition and Innovation Act (BPCIA) allows biosimilars to be approved as interchangeable with their reference biologics. However, no biosimilars have received this interchangeable status to date. Due to this lack of interchangeability, the impact of biosimilars from proposed "frozen formulary" legislation may be categorized in the "new brand medication launch" provision as a separate brand rather than a generic launch. Many states already have biosimilar substitution laws that require interchangeability, which would be activated if or when an interchangeable indication is approved. We anticipate payers may have the flexibility to cover biosimilars and remove biologics from a formulary under the "lower member cost" provision described above.

Medications experiencing midyear price increases

Currently, payers can remove medications from their formularies to shift utilization to more cost-effective medications if prescription drug prices increase significantly during the plan year. This ability to remove a medication from a plan's formulary mitigates the cost impact if pharmaceutical manufacturers were to potentially implement significant price increases and may contribute to price stability throughout the year.

Under the proposed "frozen formulary" legislation, payers would not have the ability to properly manage medications experiencing significant price increases. In particular, if the medication is subject to a flat copay, members would be insulated from the increased ingredient cost, and the payer would lack any ability to shift members' utilization to a more cost-effective and therapeutically equivalent medication. As a result, payer costs would typically increase compared to a situation in which the plan could remove or up-tier the medication during the year.

We estimate this scenario would not have a material impact on payer costs for several reasons. First, brand manufacturers have received scrutiny in recent years due to large price increases, which may limit the number of medications experiencing large price increases during the next several years. Second, most payers receive some form of inflation protection from their PBMs, which limits the financial impact to the plan. Contracted pricing terms between PBMs and brand manufacturers typically include price inflation protection, which limits the effective price increases realized by payers. This diminishes the majority of the impact caused by increased medication prices. The net payer cost remains stable, but members with coinsurance or high-deductible health plans may experience increased cost sharing. Finally, generic medications with large increases may be on Maximum Allowable Cost (MAC) lists for health plans, which would limit the amount the plan pays for a specific medication until the pharmacies are able to renegotiate contracts and agreements for the MAC lists. For these reasons, we expect the financial impact of this scenario to be immaterial.

Stakeholder behavior

The modeled provisions consider potential behavioral responses from members and payers. For example, the "new generic medication launch" provision reflects an assumed reduction in the shift from brand to generic medication use. The "new brand medication launch" provisions reflect expected changes in rebate contracting flexibility.

We did not model other payer behavioral changes that may occur if proposed "frozen formulary" legislation was enacted. If a payer is aware that negative formulary changes cannot occur midyear, then the payer may proactively negotiate formulary positions in anticipation of a future event. For example, a brand medication expecting to lose patent with generic entry in the upcoming year could be removed ahead of the next year.

Proposed "frozen formulary" legislation may impact other stakeholders in the prescription drug supply chain. For example, this proposed legislation may financially affect pharmaceutical manufacturers, wholesalers, PBMs, and pharmacies. Our analysis does not consider these or other potential changes, but we acknowledge that other behavior changes may occur and could have significant impacts on our estimates.

Benefit design

The estimated "frozen formulary" impact for a specific plan is dependent on the plan's tier-specific member cost sharing. The estimated costs above reflect a four-tier pharmacy plan with retail cost-sharing levels of $11/$35/$62/26% for generic/preferred brand/nonpreferred brand/specialty tiers. For example, we assume that, when a new generic medication launches, members will pay an $11 copay for the medication, and the payer is responsible for the remaining drug cost. Actual payer costs will differ from the estimates in this report due to variations in member cost sharing and out-of-pocket limits by plan. This plan design is informed by Kaiser's Employer Health Benefits Survey, as noted in the Methodology section below.

Other forms of formulary management

Additional forms of formulary management that were not modeled in this analysis include potential "frozen formulary" legislation for over-the-counter (OTC) medications and certain UM programs, such as prior authorization (PA), quantity limits (QL), or step therapy (ST). Proposed "frozen formulary" legislation for OTC medications would restrict the ability of payers to enact midyear formulary changes that incentivize members to use newly available OTC products. UM programs control costs while delivering necessary prescription medications. PA programs are intended to determine whether coverage is necessary and appropriate by ensuring that the medication is used in a clinically supported setting. ST programs require members to try more clinically effective or equally clinically effective and/or less costly medications (i.e., generic) first without success prior to the plan covering the selected medication. QL programs may prevent prolonged treatment that may be harmful, wasteful, or unnecessary. Proposed "frozen formulary" legislation could impact a plan's ability to implement these new programs throughout the year.

Medicare Part D formulary requirements

As a federal program, Medicare Part D is generally not subject to state legislation. However, the Medicare Part D program includes certain provisions that may be somewhat similar in nature but different operationally from the potential "frozen formulary" restrictions considered at the state level. Payers in the Medicare market are unable to enact negative formulary changes during a plan year without significant member outreach, physician outreach, and approval by CMS. Negative formulary changes include increasing member cost sharing and imposing more restrictive UM programs, such as a PA, ST, or QL. However, Medicare Part D payers may remove existing brand medications from the formulary when an equivalent generic medication is released. In addition, brand and generic medications may also be removed from the formulary if the medication is recalled as a result of safety concerns or other reasons.

Our interpretation of commercial market "frozen formulary" proposed legislation is that existing brand medications may not be removed from the formulary midyear regardless of whether a new brand or new generic medication launches. This is similar to the Medicare Part D restrictions for new brand launches, but differs from the Medicare Part D regulations for new generic launches. For example, when a new brand medication launches, Part D payers are restricted from up-tiering or removing existing brand medications from the formulary. The required commercial market "frozen formulary" provisions may vary by state. The amount of time required to implement requested midyear formulary changes may also vary by state, and may differ from CMS's approval process timing for Medicare Part D formulary changes. We did not compare the estimated commercial market financial impact of potential state-level "frozen formulary" restrictions to the impact of current Medicare policies due to the key differences and confounding variables between the two markets.

Methodology

The following section outlines the approach and key assumptions for estimating the financial impact of potential "frozen formulary" legislation on the fully insured commercial market.

APPROACH

We relied on cost and utilization experience from Milliman's 2020 Health Cost Guidelines to project average expected commercial, fully insured payer prescription drug costs for 2021 to 2025. We first projected average market costs under the current environment (baseline). We then modified the projected unit cost, utilization, and other assumptions to reflect expected changes under potential "frozen formulary" legislation. The estimated dollar impact of potential "frozen formulary" legislation to payers is the difference between the baseline and "frozen formulary" projected costs. The estimated percentage impact of potential "frozen formulary" legislation to payers reflects the "frozen formulary" projected costs compared to the baseline costs. Key assumptions for the baseline and "frozen formulary" provisions are outlined below. For the "frozen formulary" provisions, we illustrate the potential impact for a range of assumptions based on our experience and discussions with clinical experts (e.g., pharmacists).

We project pharmacy payer costs on a nationwide basis and allocate costs by state based on fully insured commercial market enrollment and pharmacy spending by state.

We modeled two distinct "frozen formulary" provisions, listed below, and assumed independence among each provision. The estimated cost of each "frozen formulary" provision reflects prescription drug costs only and does not reflect potential changes in medical costs that may result from formulary changes.

BASELINE ASSUMPTIONS

The following outlines key baseline assumptions (i.e., no "frozen formulary" change). We assume these items do not change as a result of the "frozen formulary" legislation.

- **Plan design.** Assumed a four-tier pharmacy plan with retail cost sharing of $11/$35/$62/26% for generic/preferred brand/nonpreferred brand/specialty tiers based on the 2020 Employer Health Benefits Survey of the Kaiser Family Foundation (KFF).[12] Mail-order cost sharing is assumed to be 2.5 times retail. We assume a $0 deductible and a $2,000 out-of-pocket maximum apply to the pharmacy benefit. Based on historical KFF survey results, copays were relatively consistent across years, so we apply the same plan design each year.
- **Discounts.** Assumed retail discounts from average wholesale price (AWP) of 85.0%/18.0%/18.0% and mail-order discounts of 87.0%/21.0%/21.0% for generic/brand/specialty medications. Discounts are based on industry knowledge and Milliman's Health Cost Guidelines.
- **Trends.** Assumed secular utilization trends of 1.0%/1.0%/6.0% and secular unit cost trends of 0.3%/5.0%/6.0% for generic/brand/specialty medications. Trends are based on industry knowledge and Milliman's Health Cost Guidelines. We apply secular trends to project utilization and cost for 2021 through 2025. We separately apply adjustments for generic launches (described below).
- **Rebates.** Assumed rebates of 45% of wholesale acquisition cost (WAC) for brand non-specialty medications and 20% of WAC for brand specialty medications. Rebates were reviewed for reasonability based on industry knowledge.
- **Dispensing fees.** Assumed to be $0.75 per 30-day equivalent retail script and $0 per 90-day equivalent mail-order script based on industry knowledge and Milliman's Health Cost Guidelines.
- **Generic launches**: We project savings due to generic launches by modeling shifts in brand to generic utilization and the expected generic cost post-launch. We develop individual utilization shift and cost assumptions for each generic medication where the corresponding brand has material market share. The utilization shift and cost assumptions are based on a combination of internal and external industry data. These

[12] Kaiser Family Foundation (October 8, 2020). 2020 Employer Health Benefits Survey. Retrieved January 5, 2021, from https://www.kff.org/health-costs/report/2020-employer-health-benefits-survey/

assumptions reflect the expected timing of future brand patent expirations, as well as whether the generic will be offered exclusively by a single manufacturer or competitively across multiple manufacturers. Appendix III includes a list of modeled 2021 generic launches and the associated brand medication. Due to uncertainty of future brand patent expirations, we model the impact of the "new generic medication launch" provision for 2022 to 2025 based on the expected impact for 2021.

We also model the estimated impact of future generic launches through drug utilization trends. We assume generic utilization increases by 0.5% and brand utilization decreases by 5.0% annually for 2022 through 2025 due to future generic launches. These additive trend adjustments are applied to the secular trend assumptions described above. The trends are based on industry knowledge and Milliman's Health Cost Guidelines.

Future biosimilar launches were reviewed, but were excluded from the report findings. The adoption of the biosimilar medications is dependent on various formulary management strategies by health plans and PBMs to negotiate the lowest discount between the reference sponsor and biosimilar sponsor. Biosimilar medications do not follow similar cost and utilization patterns to new generics and were therefore excluded from the generic medication launches. We discuss these medications in the Other Considerations section above.

- **Enrollment.** We estimate that 86 million members in the United States receive prescription coverage through fully insured commercial health plans for 2021. This estimate is based on 2018 U.S. Census data,[13] Kaiser's 2019 Health Care Coverage of the U.S. Population data,[14] and insured status data from the 2018 Medical Expenditure Panel Survey.[15] Enrollment trends from 2018 to 2025 are consistent with 2018 CMS National Health Expenditure projected enrollment trend rates for private health insurance in years 2018 to 2025[16] and do not vary by state.
- **State allocation.** We allocated national aggregate dollars across states using fully insured commercial enrollment by state from the sources described above, along with prescription drug cost and utilization area factors from Milliman's 2020 Health Cost Guidelines. We assume that the distribution of prescription drug medication expenditures by state remains constant from 2021 to 2025. Differences in state laws, mandated benefits, prescribing patterns, and other specific geographic variation are not reflected in this illustrative allocation.

"FROZEN FORMULARY" ASSUMPTIONS

The following section outlines our expectation of key changes under potential "frozen formulary" legislation. The assumptions presented below are based on our experience and discussions with clinical experts (e.g., pharmacists). We illustrate ranges for each key assumption due to the uncertainty of future market changes. Future experience may vary from the modeled assumptions. For example, future emergence of new brand medications is uncertain, and we illustrate a range of potential rebate changes based on historical experience.

- **New generic medication launch.** When a new generic medication launches, we expect utilization to shift from the associated brand medication to the generic. If plans were not allowed to remove the associated brand medication from the formulary when a new generic launches, we assume a 50% reduction in the utilization that would be expected to shift to the generic (35% to 65% range) based on our clinical experience. We also assume that, when an existing brand is removed from the formulary midyear, then approximately 20% to 35% of the annual brand utilization shifts away to other medications within the class. This range reflects uncertainty in the mix of brand and generic utilization due to differences in state laws and prescribing patterns.

[13] U.S. Census Bureau. State Population Totals and Components of Change: 2010-2019: Annual Estimates of the Resident Population for the United States, Regions, States, and Puerto Rico: April 1, 2010 to July 1, 2019. Retrieved January 5, 2021, from https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html#par_textimage

[14] Kaiser Family Foundation (2019). Health Insurance Coverage of the Total Population. State Health Facts. Retrieved January 5, 2021, from http://www.kff.org/other/state-indicator/total-population/

[15] U.S. Department of Health and Human Services. Medical Expenditure Panel Survey, Table II.B.2.b.(1): 2018 Percent of Private-Sector Enrollees That Are Enrolled in Self-Insured Plans at Establishments That Offer Health Insurance by Firm Size and State. Retrieved January 5, 2021, from https://meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2018/tiib2b1.pdf

[16] CMS. National Health Expenditure Data: Projected. Retrieved January 5, 2021, from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

These assumptions affect both utilization and unit cost, because we assume increased utilization on the higher-cost brand medication. The value of specific generic launches may change for future years depending on patent losses and litigations.

- **New brand medication launch.** When a new brand medication launches, we assume payers will renegotiate rebate contracts for preferred brand medications within the respective therapeutic class. When this occurs, we assume rebates for brand medications within the class increase by 20% on average after the launch of the new medication (10% to 30% range). If payers were not allowed to renegotiate rebates during the year, we assume rebates for brand medications within the therapeutic class would correspondingly decrease.

  We assume the therapeutic classes with a brand patent approval account for approximately 5% to 20% of total brand utilization per year, based on historical launch and utilization data for 2018 and 2019. We incorporate a midyear timing adjustment for this provision by assuming an average launch date of July 1 for all medications under this provision. We also assume that 50% of new brand launches are at a lower price and would be affected by the proposed "frozen formulary" legislation, based on a review of 2018 and 2019 launch information. We assume utilization for midyear brand launches remain a constant percentage of total brand utilization throughout the projection period.

  The value of rebates may vary for future years depending on the competition of newly launched brand medications, rebates offered by brand manufacturers, and the negotiation leverage of payers in controlling the utilization of formulary medications.

Caveats and Limitations

This Milliman report has been prepared for the specific purpose of estimating the financial impact of proposed "frozen formulary" legislation on payers. This information may not be appropriate, and should not be used, for any other purpose. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

The information presented in this report is provided for PCMA. PCMA may share this information with outside entities with Milliman's permission. Milliman does not intend to benefit, and assumes no duty or liability to, other parties who receive this work product. Any third party recipient of this work product who 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. This report must be read in its entirety and specialized knowledge of the industry is necessary to fully understand the report and its conclusions.

Milliman does not provide legal advice, and recommends that PCMA consult with its legal advisors regarding legal matters. The terms of Milliman's Consulting Services Agreement with Pharmaceutical Care Management Association dated August 2, 2013, and the Indemnification agreement in the engagement letter dated November 16, 2020, apply to this report and its use.

MODEL AND DATA RELIANCE

Milliman has developed certain models to estimate the values included in this report. The intent of the models is to estimate the impact of proposed "frozen formulary" legislation on payer costs. We have reviewed the models, including their inputs, calculations, and outputs, for consistency, reasonableness, and appropriateness to the intended purpose and for compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP). We also relied on expertise from numerous clinical staff (e.g., pharmacists) in evaluating this proposal and developing our modeling assumptions.

The models rely on data and information as input to the models. We relied upon certain data and information outlined below. 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.

Data and information reliance includes:

- Kaiser Family Foundation: 2020 Kaiser Employer Health Benefits Survey and the 2018 Kaiser Health Care Coverage of the U.S. Population data.
- CMS: 2018 National Health Expenditure Projections.
- U.S. Department of Health and Human Services: 2018 Medical Expenditure Panel Survey data.
- U.S. Census Bureau: 2018 Annual Estimates of the Resident Population for the United States, Regions, States, and Puerto Rico.

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.

These projections assume no material changes in the enrollment or dynamics of the commercial, fully insured health insurance market. The projections make no provision for any possible changes to healthcare requirements that may arise in the future.

ACKNOWLEDGMENT OF QUALIFICATION

David M. Liner and Tracy A. Margiott are actuaries for Milliman. We are members of the American Academy of Actuaries and meet the Qualification Standards of the American Academy of Actuaries to render this opinion. To the best of our knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

Appendices

APPENDIX I: ESTIMATED PAYER COST OF "FROZEN FORMULARY" LEGISLATION BY STATE ($ MILLIONS)

	2021	2022	2023	2024	2025	2021-2025
Nationwide	**$790**	**$930**	**$1,080**	**$1,240**	**$1,430**	**$5,470**
Alabama	$13	$16	$18	$21	$24	$92
Alaska	$2	$2	$2	$2	$3	$11
Arizona	$13	$16	$18	$21	$24	$92
Arkansas	$6	$7	$8	$9	$10	$40
California	$104	$118	$137	$156	$182	$697
Colorado	$12	$15	$17	$20	$23	$87
Connecticut	$10	$12	$14	$16	$18	$70
Delaware	$2	$3	$3	$3	$4	$15
District of Columbia	$2	$3	$3	$4	$4	$16
Florida	$49	$58	$67	$77	$89	$340
Georgia	$23	$27	$32	$37	$42	$161
Hawaii	$5	$6	$7	$8	$9	$35
Idaho	$4	$4	$5	$6	$7	$26
Illinois	$31	$37	$43	$49	$57	$217
Indiana	$17	$20	$23	$27	$31	$118
Iowa	$6	$8	$9	$10	$12	$45
Kansas	$7	$8	$10	$11	$13	$49
Kentucky	$9	$10	$12	$14	$16	$61
Louisiana	$12	$14	$16	$19	$22	$83
Maine	$3	$4	$5	$5	$6	$23
Maryland	$17	$20	$23	$26	$30	$116
Massachusetts	$20	$24	$28	$32	$36	$140
Michigan	$24	$29	$33	$38	$44	$168
Minnesota	$11	$13	$15	$17	$19	$75
Mississippi	$6	$7	$8	$10	$11	$42
Missouri	$13	$16	$18	$21	$24	$92
Montana	$2	$2	$3	$3	$4	$14
Nebraska	$5	$6	$7	$7	$9	$34
Nevada	$7	$8	$10	$11	$13	$49
New Hampshire	$3	$4	$4	$5	$6	$22
New Jersey	$27	$32	$37	$42	$49	$187
New Mexico	$3	$3	$4	$5	$5	$20
New York	$60	$71	$82	$94	$108	$415
North Carolina	$19	$22	$26	$30	$34	$131
North Dakota	$2	$2	$2	$3	$3	$12
Ohio	$21	$25	$29	$34	$39	$148
Oklahoma	$8	$10	$11	$13	$15	$57
Oregon	$9	$11	$13	$15	$17	$65
Pennsylvania	$35	$41	$48	$55	$64	$243
Rhode Island	$3	$3	$4	$4	$5	$19
South Carolina	$10	$12	$14	$16	$18	$70
South Dakota	$2	$2	$3	$3	$3	$13
Tennessee	$17	$20	$23	$27	$31	$118
Texas	$69	$82	$95	$109	$126	$481

	2021	2022	2023	2024	2025	2021-2025
Utah	$9	$10	$12	$14	$16	$61
Vermont	$1	$1	$2	$2	$2	$8
Virginia	$23	$27	$31	$35	$41	$157
Washington	$16	$19	$22	$26	$30	$113
West Virginia	$4	$4	$5	$6	$7	$26
Wisconsin	$13	$15	$18	$20	$23	$89
Wyoming	$1	$1	$1	$2	$2	$7

APPENDIX II: ESTIMATED PAYER COST OF "FROZEN FORMULARY" LEGISLATION ($ PMPY)

	2021	2022	2023	2024	2025	2021-2025
Low	$7.00	$8.50	$10.25	$12.00	$13.75	$10.25
Mid	$9.50	$11.25	$13.00	$15.00	$17.00	$13.25
High	$13.00	$14.75	$16.75	$19.00	$21.25	$17.00

APPENDIX III: MODELED 2021 GENERIC LAUNCHES

Note: These generic launches were modeled as of December 2020 and are uncertain for 2021. This list is subject to change due to on-going patent litigations, FDA approval of the generic, and other factors.

Brand Name	Generic Name	Expected Launch Year
AMITIZA	LUBIPROSTONE	2021
BROVANA	ARFORMOTEROL	2021
BYSTOLIC	NEBIVOLOL	2021
DALIRESP	ROFLUMILAST	2021
EMTRIVA	EMTRICITABINE	2021
FERRIPROX	DEFERIPRONE	2021
GILENYA	FINGOLIMOD	2021
INTELENCE	ETRAVIRINE	2021
LYRICA CR	PREGABALIN (LYRICA CR)	2021
PERFOROMIST	FORMOTEROL FUMARATE	2021
PRADAXA	DABIGATRAN	2021
SUTENT	SUNITINIB	2021
THALOMID	THALIDOMIDE	2021
VIIBRYD	VILAZODONE HYDROCHLORIDE	2021
ZOMIG	ZOLMITRIPTAN (ZOMIG)	2021

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