Pharmacy Benefit Alternative Funding Programs: key considerations for self-funded plan sponsors

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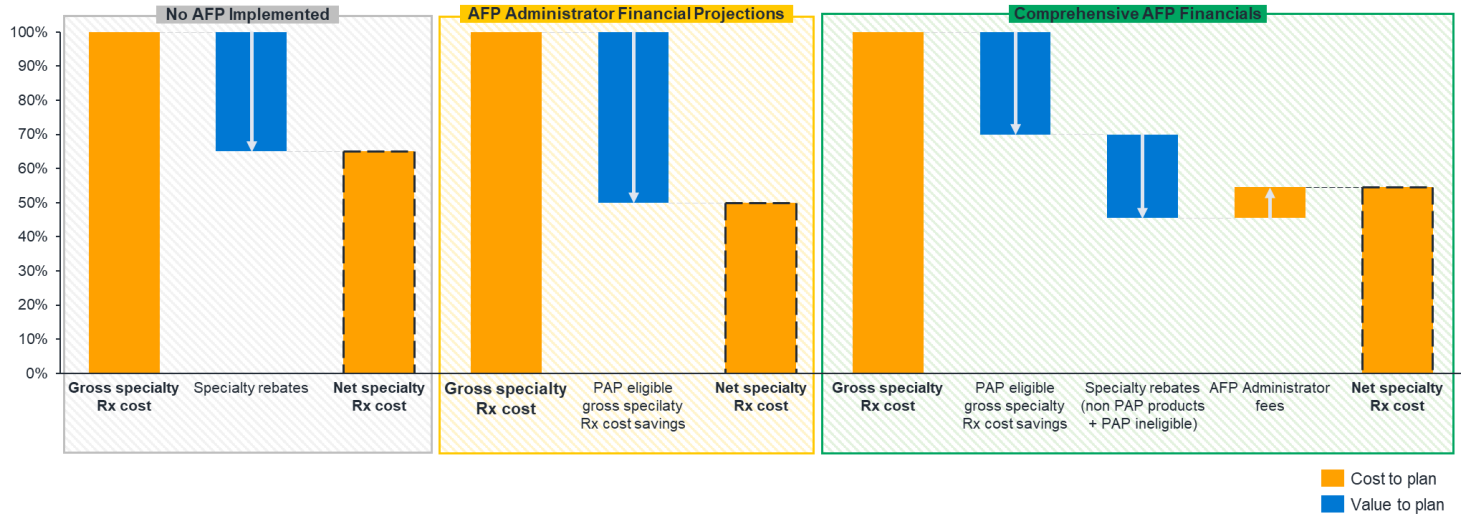
Executive Summary

The rising cost of specialty drugs has intensified payers' interest in innovative cost management solutions. Alternative funding programs (AFPs) have emerged as a solution to growing specialty drug spend and often project significant savings for self-funded plan sponsors. Plan sponsors exclude pharmacy benefit coverage for select high-cost drugs and direct plan members to work with AFP administrators to access those drugs. AFPs often leverage manufacturer patient assistance programs (PAPs) to offset the cost of these drugs for plan sponsors. However, plan sponsors should examine the methodology used to calculate savings projections to determine if those savings are achievable for their plans. In this whitepaper, we provide an illustrative example that demonstrates how net specialty drug costs using an AFP can be similar to net specialty drug costs without an AFP when taking into consideration the percentage of lives that may not be eligible for PAPs, manufacturer rebates, and AFP administrator fees.

Figure 1. Illustrative example of net specialty pharmacy benefit cost for a plan engaging in an AFP



When assessing the implementation of an AFP, plans may consider evaluating various elements that may not be included in an AFP administrators' savings projections to have a more holistic understanding of the financial implications to the plan. The comprehensive financial impact should be evaluated in tandem with compliance considerations, assessments of member impacts, as well as interactions with other vendors, including the plan sponsor's pharmacy benefit manager (PBM) and stop loss vendor. Plan sponsors may consider:

- Asking the alternative funding program administrators if the quoted savings projections account for rebates, member income mix, and AFP administrator fees. If the savings projections do not, realized savings may be lower than advertised.
- Reviewing the program details with legal and compliance professionals to ensure the plan and its members remain compliant with all applicable laws and regulations.

- Discussing the proposed AFP with the plan sponsors' PBM and stop loss carrier. Exclusion of high-cost specialty drugs and subsequent coverage through AFPs may impact stop loss claim eligibility or premiums.

Background on Alternative Funding Programs

Specialty drug costs have grown considerably in the last decade and are projected to continue to increase over the coming years, driven by new product launches, expanded indications for existing therapies, and an increase in the number of people prescribed specialty drugs.[1] Total specialty drug expenditures in the United States increased to $301 billion in 2021, a 43% increase from 2016.[2] Although specialty medications make up a small portion of total drug utilization (2 to 3%), they account for a disproportionate amount of total drug spend (51 to 60%).[3,4] The growing cost of specialty medications poses a challenge for self-funded employers, who are financially responsible for most of the cost of these therapies.

Alternative funding programs (AFPs) have emerged as a cost containment solution to mitigate the growing cost of specialty products for self-insured plan sponsors. Alternative funding aims to leverage manufacturer patient assistance programs (PAPs) to offset the cost of certain high-cost drugs for plan sponsors. A general description of a common AFP design is as follows: plan sponsors exclude pharmacy benefit coverage for select high-cost drugs, generally specialty medications, and direct plan members to work with AFP administrators to access those drugs.[5] AFP administrators primarily secure funding for the selected high-cost drugs through patient assistance programs (PAPs) – programs to provide low-income and uninsured individuals access to prescription drugs.[6,7]

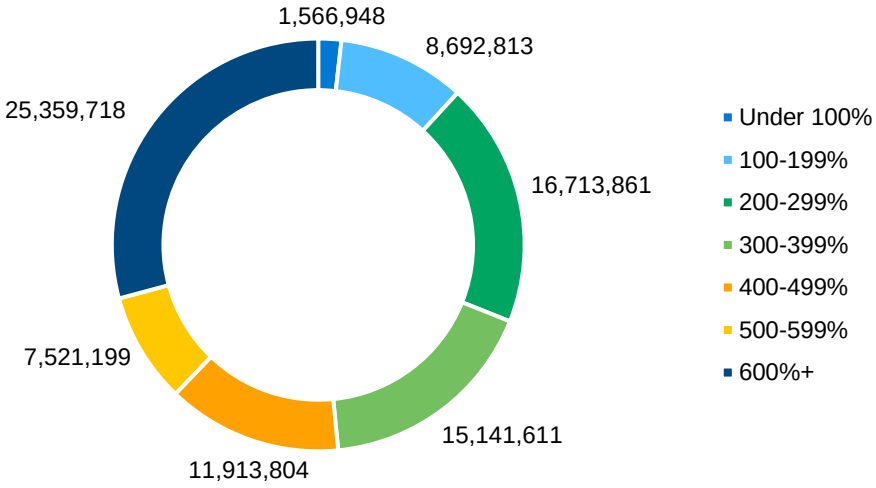
PAPs are most frequently sponsored by individual manufacturers (e.g., AbbVie Patient Access Support, Lilly Cares)[8,9] but can also be sponsored by independent organizations (e.g., PAN foundation).[10] These programs are generally intended to provide medications to people with limited or no health insurance who demonstrate financial need. As such, patient-specific income level is often considered when evaluating a patient's eligibility for these programs.[11] There is some variability in the income thresholds across PAPs, and even within a given PAP for different products.[12] Income criteria to assess PAP eligibility is typically tied to a percentage of federal poverty level (FPL), and often ranges from 300 to 600% of the FPL, as outlined in Figure 2 below. For reference, the 2023 FPL for a family of four is defined as a household income of $30,000.[13] However, based on the top ten specialty drug manufacturers by gross spend[14] that publish income requirements, patients generally must have an income less than 500% of the FPL to be eligible for PAP funding.[15,16,17,18]

Figure 2. PAP characteristics across manufacturers of the top 10 specialty drugs by gross spend[19]

Manufacturers	Top specialty drugs	PAP explicitly prohibits AFPs	Income requirements (% of FPL)
AbbVie	Humira, Skyrizi	Yes[20]	600%[21]
J&J	Stelara, Remicade, Tremfya	Yes[22]	300 to 600%[23]
Merck	Keytruda	No	400 to 500%[24]
Genentech	Ocrevus	Yes[25]	Not publicly available
Sanofi	Dupixent	No	400%[26]
Takeda	Entyvio	Yes[27]	Not publicly available
Amgen	Enbrel	No	300% to 500%[28]

To determine eligibility for a PAP, patients are often required to submit personal details to the PAP, including financial data (e.g., household income, credit checks), and health-related information pertinent to their requested prescription.[29,30,31,32] Figure 3 shows the number of self-funded employer lives by FPL. Approximately 32.9 million self-funded employer lives, or 38%, are over 500% of the FPL, indicating these individuals may be ineligible for many of the most financially impactful PAPs due to income.[33]

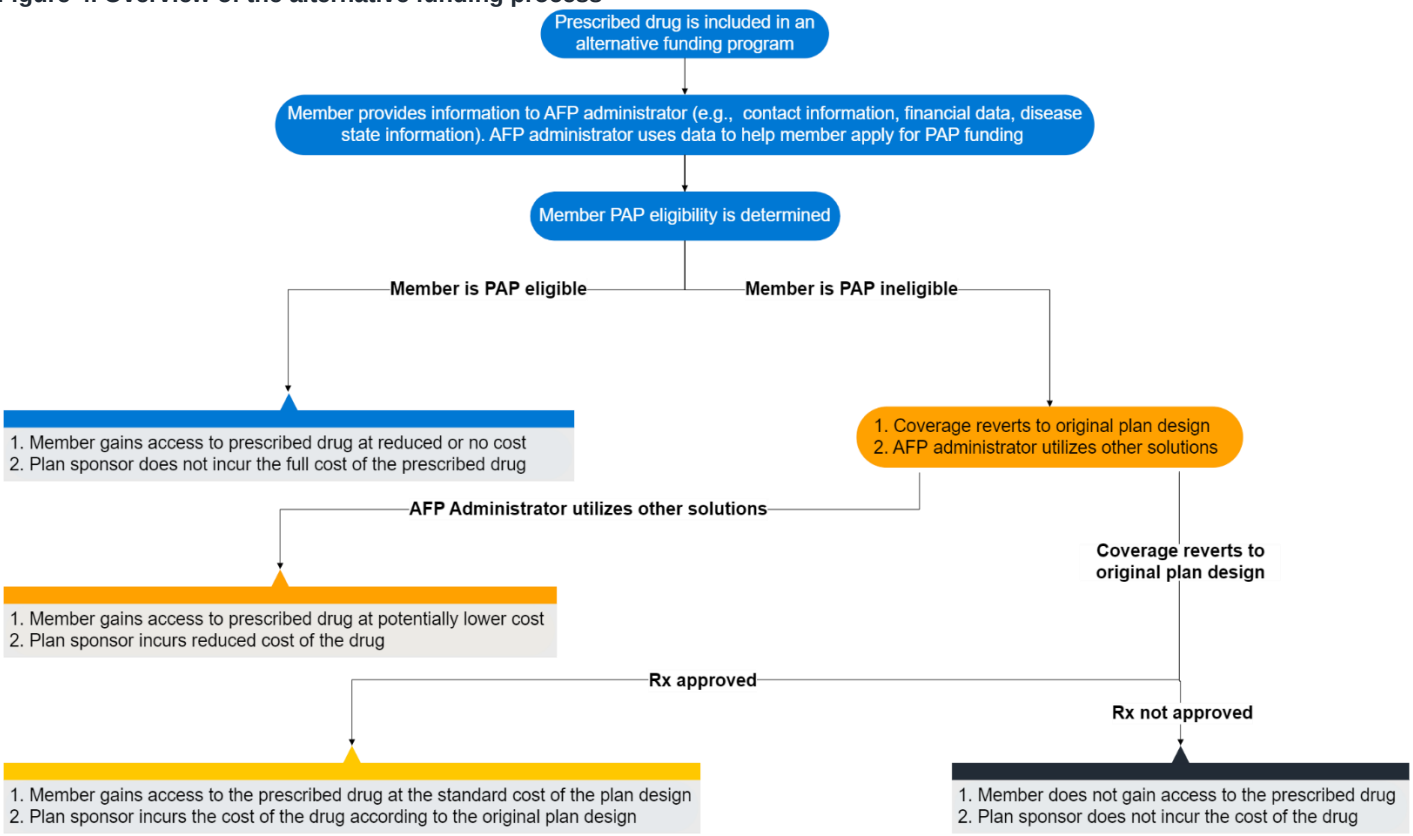
Figure 3. Self-funded plan sponsor lives by FPL in 2022[34]



Source: Internal Milliman analysis that relied on data from KFF, the Employee Benefit Research Institute, and the 2022 U.S. Census Bureau

If a member is not eligible for PAP funding, the AFP administrator may utilize other approaches to help the member access the drug or the employee's plan may cover the product under its traditional plan design.[35,36] The AFP generally does not integrate into the pharmacy benefit. Rather, it operates outside the employer's plan as a standalone program only used for certain pre-defined specialty products. Depending on the AFP, the execution of PBM-facilitated utilization management may be impacted.[37] Some utilization management, specifically prior authorizations, may be conducted by AFP administrators.[38] However, if utilization management (e.g., prior authorizations) is reduced or eliminated, drug utilization may increase. Figure 4 outlines the typical member journey for those members who access specialty medications through an AFP.

Figure 4. Overview of the alternative funding process[39,40,41,42]



As AFPs have gained traction, there has been an increase in manufacturer scrutiny of these programs.[43,44] AFPs receive the vast majority of their funding from manufacturer sponsored PAPs, with less than 1% coming from charitable foundations.[45] PAPs are designed to help patients with limited or no health insurance coverage gain access to their prescriptions. As such, some believe AFPs are diverting PAP funding from patients in need to reduce employer costs.[46,47] AbbVie, Eli Lilly, Genentech, Janssen, and Takeda have updated their eligibility criteria for patients to qualify for PAP participation, explicitly stating that patients are ineligible for PAP funding if they participate in an AFP or similar arrangement that provides conditional coverage upon application to a PAP.[48,49,50,51,52] In one case, a manufacturer has sued AFP vendors claiming the program threatens the sustainability of PAPs.[53] As these manufacturers produce some of the top specialty drugs by spend, their products account for a significant portion of the specialty drug spend in the U.S.[54] These limitations on PAP-eligibility for members who are enrolled in an AFP can have a material impact on the financial value of these programs.

Financial Considerations

AFP administrators project significant specialty drug cost savings, typically ranging from 20 to 30% of specialty drug spend but as high as 70%.[55,56,57,58] AFPs may enable plan sponsors to remove a portion of high-cost specialty spend, while still supporting access to specialty medications for members who are PAP eligible. However, there are other costs that may not be incorporated in projected savings. For example, AFP savings projections may not include AFP administrator fees, the opportunity cost of lost rebates, and the effects of plan-specific income and drug mixes on member PAP eligibility.[59,60] Understanding the financial implications of AFPs is paramount for employers that are considering this type of specialty medication cost management strategy.

AFP ADMINISTRATORS' SAVINGS METHODOLOGY

The methodology to calculate fees and savings varies among AFP administrators. It is essential that plan sponsors understand how AFP administrators' savings are calculated and whether those calculations include the full scope of potential program costs. For example, drug rebates often materially contribute to lowering the net specialty drug cost for plans, generally reducing gross specialty cost by approximately 35%.[61] Rebates vary by drug and generally depend on how that drug is covered (e.g., formulary placement, utilization management); however, not all plan sponsors have full transparency into drug-level rebates.[62] Additionally, rebate payments from PBMs to plan sponsors are dependent on the plan sponsor's individual PBM contract. The most common rebate arrangement is 100% pass-through of rebates to the plan sponsor, with a minimum rebate guarantee; however, approximately 17% of clients receive fixed

rebate guarantees that may be less than 100%.[63] AFP savings projections may not account for impacts to plan rebates,[64] considering the variability of drug-level rebates and low-levels of transparency. Plan sponsors often lack visibility into their members' total household income.[65] As a result, savings projections may not account for PAP ineligibility due to plan-specific income mixes. Lastly, AFP administrator fees may not be included in saving projections, as seen in one AFP administrator's invoice example.[66] Variability in the alternative funding savings projections methodology can affect a plan's ability to realize the full projected savings.

Employer consideration: Ask your AFP administrator if their savings projection accounts for rebates, your plan's unique member income mix, and AFP administrator fees. If no, it may materially decrease your realized savings compared to what is projected.

Plans may consider the following when determining the financial implications of implementing an AFP:

Rebate Value: Projected savings associated with AFPs may not account for the impact to plan rebates.[67] Rebates can significantly reduce plan costs. For a plan that receives 100% of rebates from their PBM, the rebates on specialty drugs are estimated to be 35% of the specialty gross costs.[68] When considering the savings from an AFP, plan sponsors should understand the true net cost of their current specialty drug spend, taking into account the effect of rebates, to understand the impact of implementing an AFP.

Ineligible members: the portion of members who are ineligible for PAPs, either due to income or other PAP criteria, may limit AFP savings for plans assuming initial savings projections do not account for plan specific income mixes.

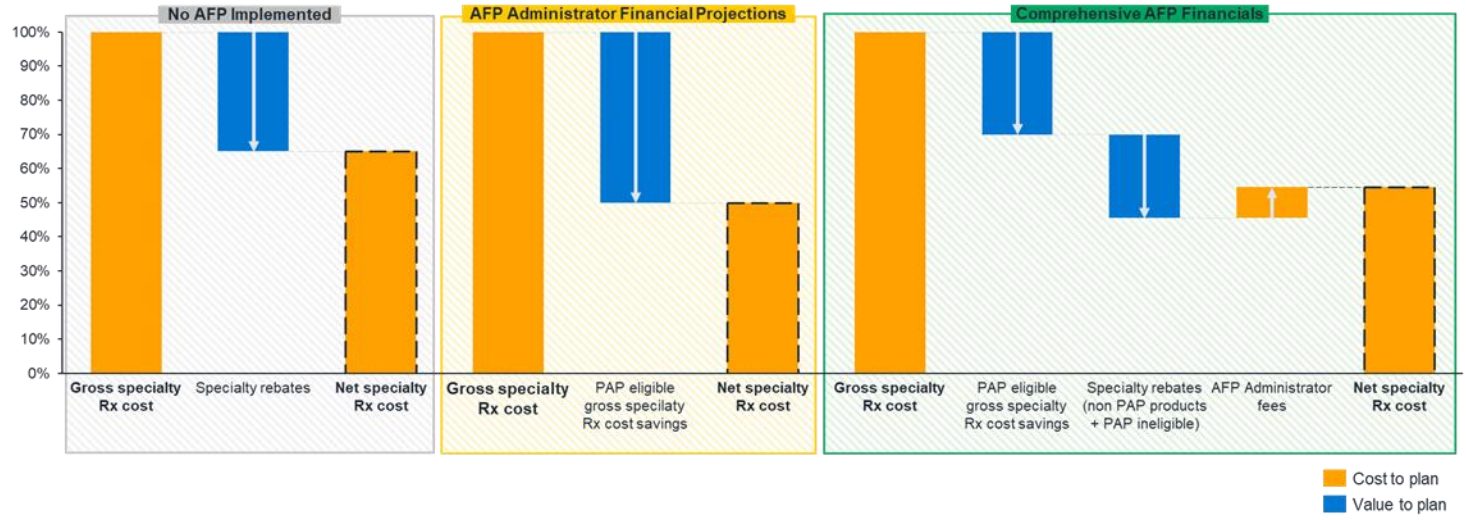
- **Income level thresholds:** One AFP administrator stated that over 80% of the patients they work with meet eligibility criteria for alternative funding;[69] however, individual plans' mix of income levels may cause this to vary widely. According to our analysis of United States Census Bureau's household incomes for full-time, year-round employees, over 40% of self-insured plan members are likely ineligible for PAP funding. For plan sponsors that cover members who generally have income levels under 400% of FPL (i.e., $124,800 household income for a family of four),[70] most members will meet income level thresholds set by PAPs.

Increased administrative fees: AFP administrator fees are a net new fee to plans. Additionally, PBM admin fees may increase for the plan sponsor.

- AFP administrators collect fees that typically range between 20 to 35%.[71,72,73] This fee is generally applied as a percentage of the savings earned from PAP savings, although some vendors may use a per-member-per-month (PMPM) fee.[74] Some AFP administrator fees may be capped at an annual fee per prescription per plan participant per year.[75]
- Increased coordination on behalf of the PBM may include manual overrides for members who are ineligible for PAP funding. Depending on the plan sponsor / PBM agreement, this increased oversight may result in increased admin fees.[76,77,78]

Figure 5, below, is an illustrative example outlining the comprehensive drug spend for a plan engaging in an AFP. When accounting for reduced rebate revenue, members who are ineligible for PAP funding, AFP administrator fees, and the potential for increased admin fees, savings projected by AFP administrators to plan sponsors may be overstated. For this example, we assumed a 35% specialty rebate, 50% advertised PAP savings, 40% PAP ineligibility, 30% AFP administrator fees, and no change to PBM admin fees.

Figure 5: Illustrative example of net specialty pharmacy benefit cost for a plan engaging in an AFP



Please note, the comprehensive AFP financial scenario assumes that PAP ineligible products receive a rebate when processed under the employer plan design; however, it is possible that the employer would not receive rebates for these products if they are non-formulary. This has the effect of further increasing the net specialty pharmacy costs, relative to the AFP administrator projections. Varying PBM / plan agreements will impact the opportunity cost of rebate revenue depending on how rebates arrangements are structured.

Employer consideration: Ask the AFP administrator and PBM who will coordinate utilization management controls during the alternative funding process and when this process will occur. If utilization management (e.g., prior authorizations) is reduced or eliminated, drug utilization may increase.

Actual savings may also differ among plans based on plan sponsor demographics. The overall rates of PAP eligibility will be influenced by specific member demographics and drug utilization mixes. Plans with a higher proportion of low-income members or larger market share of drugs with high-income eligibility criteria (e.g., 500 to 600%) may have larger rates of PAP eligible patients, and therefore, higher savings from AFPs. Lastly, participating in an AFP may preclude a plan sponsor from participating in other specialty cost containment solutions under the non-AFP arrangement, but these impacts are not modeled here.

Additional Considerations

POTENTIAL COMPLIANCE RISKS

There are also a handful of potential compliance risks associated with implementing an AFP that plan sponsors should consider:

- **Income discrimination:** plans may inadvertently provide expanded coverage disproportionately to highly compensated individuals.[79,80,81]

  When a member is denied PAP funding for a select product through an AFP, the member's coverage for the product may revert to the traditional plan design.[82,83] Plans and AFP administrators often set up benefit designs this way to ensure that members do not experience disruption in coverage, regardless of PAP eligibility. Given that household income above eligibility thresholds is a significant cause of PAP ineligibility, plans are often left covering products for high-income members while simultaneously excluding coverage for the same products for low-income members. This leaves plans vulnerable to violating the nondiscrimination protections of Section 105 of the Internal Revenue Code of 1986, which requires that "a self-insured medical reimbursement plan does not meet the [nondiscrimination requirements] unless all benefits provided for participants who are highly compensated individuals are provided for all other participants."[84]

- **Tax implications:** plans may have additional reporting and withholding requirements to comply with tax laws.

  There may be tax implications for employers who provide coverage of excluded specialty medications for members who are ineligible for PAPs. Typically, health insurance benefits provided through a written plan are excluded from a members' gross income. However, for employers who exclude coverage of certain specialty medications and participate in an AFP, subsequent employer coverage of the drug cost for the member who was determined to be ineligible for a PAP may be considered excess reimbursement of highly compensated individuals under Section 105 of the Internal Revenue Code of 1986. This excess reimbursement amount would then need to be reported in gross income on the employee's W-2. This would result in additional federal income and employment tax liability for the affected employee.[85] Depending on the amount of excess reimbursement, the employee may be pushed into a higher tax bracket and have access to certain tax credits and deductions reduced or even eliminated.[86] If additional income tax amounts are not withheld from employee paychecks, then the employee may also be subject to underpayment penalties as well.[87] However, the tax increase would be limited to some degree if the employee itemizes deductions to less than 10% of adjusted gross income, which includes the medical expense reimbursement.[88]

- **HIPAA compliance:** plans may assess their benefit design to ensure compliance with laws to protect against health discrimination.

  Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), members cannot be denied eligibility or benefits based on "health factors" when enrolling in a plan and cannot be charged more than similarly situated individuals based on any health factors. While plans are permitted to exclude coverage for certain types of treatments, those exclusions are required to be applied uniformly to all similarly situated individuals.[89] By excluding coverage for a list of specialty drugs that treat select conditions only for a select set of individuals (those able to obtain assistance from a PAP), a plan may be at risk, particularly if those members were more likely to need those medications, it could be construed the plan discriminated against these participants based on "health factors".

- **Fiduciary responsibility:** plans may assess the impact to their fiduciary responsibility, ensuring they prioritize providing benefits and covering reasonable administrative expenses.

Under the Section 404 of the Employee Retirement Income Security Act of 1974 (ERISA), plan sponsors have a fiduciary duty to provide benefits to participants and beneficiaries and defray reasonable expenses of administering the plan.[90] Some have argued that plans may not be able to meet their fiduciary duty if they prioritize plan savings through an AFP rather than "acting solely in the interest of the participants; for the exclusive purpose of providing benefits to participants."[91,92]

Employer Consideration: Review the AFP with legal and compliance professionals to ensure the plan and its members remain compliant with all applicable laws and regulations.

INTERACTION WITH STOP LOSS

For self-funded employer plan sponsors, the plan sponsor assumes the financial risk for the healthcare costs of its members. As such, many self-funded plan sponsors purchase stop loss insurance to mitigate against the risk of high-cost claims, either at the claim level or in aggregate. Stop loss insurance is typically limited to healthcare expenditures that are covered by the plan. If an employer were to exclude coverage of certain high-cost drugs as part of an AFP, stop loss insurance may not cover high-cost claims for drugs paid for by the plan sponsor for members ineligible for PAPs.[93,94,95]

Employer consideration: Discuss AFP participation and its impact on stop loss coverage and premium with the stop loss carrier. Exclusion of high-cost specialty drugs and subsequent coverage through AFPs may impact stop loss liability. Some stop loss carriers may offer premium reductions because of AFP participation.

MEMBER IMPACT

AFPs introduce an intermediary process for patients to work through prior to receiving their medications. The process for patients to gain coverage – by way of PAP or a reversion to the original plan design – can often take weeks.[96,97,98] One vendor stated that it could take anywhere from 24 hours to 3 weeks for a patient to obtain alternative funding, depending on how quickly the patient, provider, and PAP complete the required steps.[99] Some have cited that AFPs increase the complexity of the benefit design for members, and may be difficult for members to navigate.[100,101] The high-cost products that AFPs target are generally specialty drugs indicated for complicated, chronic illnesses.[102,103] Some have expressed concern that the delay in treatment can lead to serious health consequences for members.[104,105,106] Some AFPs mitigate the risk of delayed therapy by allowing transition fills while patients navigate the process of obtaining alternative funding and receiving their medication.[107,108]

Conclusion

Although AFPs can help manage plan sponsor costs for high-cost drugs while still providing access to those drugs, plan sponsors may consider conducting financial and compliance due diligence efforts prior to launching an AFP. The savings associated with AFPs may be lower than projected when all financial considerations are accounted for – including lost rebate revenue, PAP ineligibility, and increased administrative fees. Plan sponsors may consider taking the following actions to assess the potential savings from alternative funding programs:

- Ask the AFP administrator how they project savings and their expected fee levels and consider whether they have taken into account important components of cost or savings reductions.
- Review the plans' PBM contract for rebate pass through terms. If the plans receives no or fixed pharmacy rebates, alternative funding savings may be relatively higher, compared to if the plan receives 100% pass through of rebates.
- Review the plans' PBM contract to assess if there are increased PBM fees associated with executing an AFP. If the PBM charges additional fees for coordination with an AFP administrator, it could decrease expected savings.
- Ask the PBM about rebate eligibility on claims that are paid through the plan benefit due to denied PAP funding. If these claims are rebate ineligible, the alternative funding realized savings may be lower than projected.
- Ask the AFP administrator and PBM who will coordinate utilization management controls during the alternative funding process and when this process will occur.
- Ask the AFP administrator about the member experience and if they expect delays in therapy. Some administrators may utilize transition fills under the current benefit while members wait for medications.
- Consider the member population's compensation. If the member population is generally under 400 to 500% of FPL, then the realized savings may be relatively higher under an AFP.
- Review stop loss policy for coverage terms and conditions. Discuss AFP participation and its impact on stop loss coverage and premiums with the plan's stop loss carrier.
- Ask the stop loss provider if they have preferred rates for utilization of AFPs.
- Review AFP with legal and compliance professionals to ensure the plan and its members remain compliant with all applicable laws and regulations.

The alternative funding landscape is expected to continue to evolve as manufacturers continue to refine the parameters for program use. These considerations may help plan sponsors assess AFP program participation.

Caveats and Limitations

This report is intended to outline the considerations for self-funded plan sponsors implementing a pharmacy benefit alternative funding program. This information may not be appropriate, and should not be used, for other purposes.

Nothing in this material should be construed as legal advice or strategic recommendations, and instead are general considerations. Any third-party recipient of this report desiring professional guidance should not rely upon Milliman's work product but should engage qualified professionals for advice appropriate to its specific needs. Milliman does not endorse any public policy of advocacy position on matters discussed in this report. Special knowledge of the pharmacy supply chain is necessary to fully understand the report, and such this material assumes the audience is familiar with pharmacy alternative funding programs.

Any releases of this report to a third party should be in its entirety. If this report is referenced, it should be made available in its entirety, to avoid information potentially being misinterpreted due to being out of context.

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