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The Present and Future of Alternative Funding Programs for Specialty Drugs

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Introduction

Employers generally want to provide comprehensive medical and pharmacy benefits to their employees, but many organizations and their employees are struggling to cover healthcare costs. In 2018–2023, the average annual premium for family coverage in the commercial market increased by 22 percent. In 2024, employer healthcare costs are expected to continue increasing. In recent years, alternative funding program (AFP) vendors have emerged as a means for employers to offset drug spending for beneficiaries of their employer-sponsored plan. Although the inner workings and operating procedures of AFPs generally lack transparency, what we do know raises a slew of important questions related to legality, sustainability of cost shifting, the general lack of patient-centeredness in our healthcare system, and what we should be thinking about regarding the proliferation of AFPs.

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Frequently Asked Questions

Let's start with some frequently asked questions.

Who are the players?

In short, employers, AFP vendors, patient assistance programs (PAPs), and (to some extent) brokers. And, of course, the person needing medication (sometimes known as a beneficiary, employee, or patient, depending on the audience).

How do beneficiaries traditionally access specialty drugs?

To explain how AFPs work, we need to take a step back and describe how beneficiaries access specialty medications using employer-sponsored insurance (without the involvement of an AFP). Let's say someone is diagnosed with a specific type of cancer that can be best treated with a specialty drug. The oncologist prescribes the drug, and a claim is submitted on behalf of the beneficiary. The beneficiary will then be subject to typical patient copays, coinsurance, deductibles, and prior authorization processes as outlined in the employer's pharmacy or medical benefit provided by their employer.

In some cases, people can use assistance through PAPs to pay for the cost of drugs. PAPs are typically sponsored by pharmaceutical manufacturers, foundations, or charitable organizations. They were created to provide financial assistance to low-income or uninsured individuals who are unable to afford the cost of their medications. Eligibility criteria (established by each PAP) typically depend on a variety of factors, such as income level, insurance status, and specific medical needs.

How do beneficiaries access specialty drugs when an AFP is involved?

When an employer is using an AFP vendor, beneficiaries will be diverted from their normal pharmacy or medical benefit to work with the AFP directly. The AFP will then seek financial assistance to pay the cost of the drug on behalf of these individuals. The employer has a contractual relationship with the AFP that usually reflects shared savings or a per member per month charge.

AFPs that cannot get a PAP (or another similar charitable organization or foundation) to provide the prescription drug for free might turn to other avenues for coverage, such as through international importation via the Food and Drug Administration's personal use policy to obtain drugs. If all else fails, either the prescription will be sent back to the employer-sponsored health plan and covered like a normal pharmacy benefit or the individual will be expected to pay the cost themselves. This process of identifying and applying for assistance can be time-consuming and stressful, leading to delays in timely treatment and potentially deterioration in health status.

Are AFPs a type of insurance?

When a beneficiary is prescribed a specialty drug for which their employer has contracted with an AFP, the AFP will contact the beneficiary to pursue other avenues to pay for the drug from an alternative source. AFPs are *not* offering an insurance product, but rather direct insured individuals to alternative sources for their medicines. Therefore, this practice—which diverts the cost of certain prescription drugs away from an employer—is not regulated as an insurance product and is not subject to the oversight that generally governs health insurance. At this point, beneficiaries are not moving through their insurance benefit (as they typically would without an AFP), so any patient spending incurred is not guaranteed to apply to their deductible or out-of-pocket maximum. Many insurers are obligated to follow reporting and disclosure requirements, whereas AFPs are not currently required to follow these transparency rules because they are not technically an insurance product.

How is the presence of an AFP communicated to beneficiaries?

Though AFPs generally operate with the goal of identifying alternative funding for specialty drugs, their methods vary widely and often lack of transparency regarding specific strategies used when working with employers or tapping into new funding sources.

In some instances, a beneficiary will be informed at the beginning of the benefit year (e.g., through a benefit guide) that some or all specialty drugs will not be covered by their medical or pharmacy benefit but will instead be subject to a separate process through an AFP vendor.

In other cases, the employer will not communicate in advance to beneficiaries that these specialty drugs have been carved out of their pharmacy benefit. Rather, when a beneficiary needs one of these drugs, the medication is subject to prior authorization, which is automatically denied and rerouted to the AFP vendor. This practice was devised to circumvent rules regarding any subsequent drug costs that a PAP or other source does not cover under an employer's stop-loss coverage.

Things to Be Thinking About

Use of AFPs is not currently widespread; however, adoption is likely to increase.

Secondary research (see here and here) suggests that only a small portion of large employers now use AFPs, but nearly one in three businesses claim to be exploring this option. Our survey, though limited in scope, found that 75 percent of employers that currently use an AFP will continue their use in future benefit years. Though AFPs may have enjoyed some anonymity from oversight while attracting more employer clients (at times, via brokers), growth could mean increased regulatory and legislative attention. In fact, AFPs already are being noticed by pharmaceutical manufacturers that are uncovering threats to PAPs from AFP business practices.

On May 5, 2023, the pharmaceutical manufacturer AbbVie filed a lawsuit against Payer Matrix, an AFP vendor, alleging that it was "operating a fraudulent and deceptive scheme to enrich itself by exploiting AbbVie's PAP through the enrollment of insured patients into a charitable program not intended for them." AbbVie went on to state that "Payer Matrix… charges the patient's employers a substantial fee for reducing the employers' health insurance costs through its scam on AbbVie's PAP and other pharmaceutical manufacturers' patient assistance programs."

AFP methods are reportedly becoming increasingly aggressive as PAPs and foundations tighten eligibility requirements. In some instances, the AFP will go to great lengths to not disclose its relationship with an employee or its intent to cover drugs in the event funding is unavailable. The AbbVie v. Payer Matrix suit further alleges that the AFP attempts to convince prescribers to change their orders to alternatives for non-therapeutic reasons that financially benefit the AFP.

In recent years, alternative funding program (AFP) vendors have emerged as a means for employers to offset drug spending for beneficiaries of their employer-sponsored plan.

The financial implications for employers are ambiguous.

Though some employers and brokers may perceive AFPs as a potential cost-saving measure, concrete evidence supporting this view is limited. Our survey of employers revealed that although a notable percent of brokers see AFPs as beneficial in reducing costs, less than half of the employers that use AFPs reported a reduction in specialty drug claims. Based on the survey design, a direct correlation between the use of AFPs and an observable reduction in specialty drug claims cannot be established. Many factors could contribute to reductions in employer drug spending, such as demographic shifts in beneficiary pools, employee assistance programs, access to health management programs, or other changes to employer-sponsored benefits. Furthermore, the administrative delays associated with AFP processing could significantly increase overall individual spending. For instance, delays in funding for a critical treatment for a cancer drug might necessitate interim treatment such as radiation, which can cost more in the long run. This practice not only may expose patients to harm but also may increase total healthcare expenditures.

Beneficiaries absorb administrative burden and potentially bear high costs.

For patients, bearing the administrative burden of accessing care through our fragmented systems of care already can be a challenge. AFPs introduce another administrative process to access a specialty drug at a particularly vulnerable moment. Moreover, the beneficiary may end up paying for the drug if the AFP is unsuccessful and it's unclear whether these out-of-pocket expenses or savings from the PAPs would go toward the individual's deductible or out-of-pocket maximum. So not only might a beneficiary have to pay out of pocket for a specialty drug, but the individual may also continue to pay for other drugs and services because these costs have not been applied to their deductible or out-of-pocket maximum.

As mentioned previously, delays in treatment because of AFP processes could lead to further deterioration and/or unintended complications, such as surgical or other non-pharmaceutical interventions. These costs would likely be subject to the employer's medical benefit, resulting in unintended costs to the employer.

AFPs threaten the existence of programs aiding uninsured and underinsured populations.

PAPs are ultimately absorbing the costs of specialty drugs that the AFPs obtain. As a result, AFPs could threaten the long-term sustainability of charitable PAPs and foundations. (Ironically, by depleting PAP funds, AFPs threaten their own financial viability; if PAPs don't exist, neither can AFPs.)

Representatives of manufacturer PAPs who we interviewed described a marked increase in commercially insured patients applying for assistance. Although they were unable to attribute this increase directly to AFPs as opposed to other changes on the market (including copay accumulators and maximizers that are increasing out-of-pocket spending for consumers), they stressed that increased requests for assistance drain available funds and require additional administrative costs to process the applications.

Some PAPs are making eligibility criteria more stringent to weed out applications from commercially insured individuals, some of whom they have identified as working with AFPs. Other PAPs are changing their eligibility criteria to restrict access to patient assistance for commercially insured individuals altogether. These changes could inadvertently affect underinsured people *not* working with an AFP from accessing the drugs they need. Some manufacturers, as mentioned in AbbVie v. Payer Matrix LLC, are taking notice and going so far as to file lawsuits against specific AFPs.

Conclusion

AFP vendors have identified a growing opportunity to contract with employers that are attempting to keep their health costs down while also trying to provide access to high-cost drugs for their employees. Even in facilitating this access, the AFP approach may introduce or exacerbate other challenges in healthcare, such as disparities in care, health equity, lack of transparency, administrative burden, and lack of patient-centeredness. Such a result may lead to continued rising costs, poorer health outcomes, and increasing friction for employers and their covered employees.

The complexity and lack of clear regulations around AFPs raise questions about their long-term viability and the ethical implications of cost-shifting practices. Furthermore, though AFPs may seek to provide short-term financial relief for some employers, their effectiveness in reducing overall healthcare costs remains unproven. The potential delays in treatment caused by the administrative processes of AFPs could inadvertently lead to higher healthcare expenses and negatively affect outcomes of care.

Moreover, the growing use of AFPs places additional strain on PAPs, jeopardizing their ability to provide financial support to the patients they were designed to support. As AFPs become more prevalent, the long-term sustainability of PAPs and other charitable foundations is at risk, potentially resulting in stricter eligibility criteria that could exclude people in genuine need. The marked increase in commercially insured patients applying for assistance is not going unnoticed by PAPs, and they intend to take action to protect the sustainability of their funds.

As employers and brokers explore the use of AFPs, it is crucial that they understand the impacts AFPs can have on health outcomes, potential costs due to delayed or deferred care, strain on employee relations, and the legal and ethical risks. All stakeholders should consider the broader implications of AFPs on the healthcare system. Ensuring transparency, improving oversight, and supporting a focus on patient care should be paramount as this industry evolves.

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