



Alternative
Funding Programs

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*A resource for consumers, caregivers,
and health care providers*

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WHAT ARE ALTERNATIVE FUNDING PROGRAMS?

When a health plan partners with an alternative funding program, the health plan defines all specialty medications as [non-essential health benefits](#) (non-EHB).¹ By defining specialty medications as non-EHBs, health plans inform enrollees that they must either enroll in the alternative funding program or be responsible for 100 percent of the cost of the medication.² Because this medication is defined as a non-EHB, any cost paid for the medication by or on behalf of the enrollee will not count towards their deductible or annual limit on cost-sharing.³ Given this coercive program design, plan enrollees are essentially required to enroll in the alternative funding program.

Once enrolled with the alternative funding program, the health plan will often automatically deny coverage for the enrollee's prescription medication.⁸ In some cases, it may appear that the PBM or the alternative funding program is providing the automatic denial. Once the denial is received, the alternative funding program then steps in and obtains the enrollee's personal information, such as household size and annual income, to determine the type of third-party financial assistance the plan enrollee may be eligible for. Unlike typical non-EHB programs, which primarily enroll plan enrollees in manufacturer copay assistance programs, alternative funding programs primarily target **patient assistance programs (PAPs)**. Typically, PAPs provide eligible consumers with their prescription drug, free of cost, and ship the medication directly to consumers. These programs typically require consumers to be *uninsured or underinsured*.



If an enrollee is not eligible for the PAP, the alternative funding program may also require the individual to apply (or apply on behalf of the individual) to **manufacturer copay assistance programs** or try and source the medication from an **international importation program**.⁹

If an individual is eligible for a manufacturer copay assistance program, the health plan will inflate the copay requirement for the prescription drug to the maximum amount of manufacturer copay assistance available for the year. If the enrollee is eligible for international importation, then the enrollee will receive their medication directly through an international pharmacy.

In some cases, if the enrollee is not eligible for any part of the alternative funding program, then the prescription will be sent back to the health plan or PBM for coverage and the medication will be covered like a regular pharmacy benefit.¹⁰ For other enrollees, the plan may continue to deny coverage for the medication even after the consumer has been denied by all potential alternative sources.



Alternative funding programs are structured very similarly to non-EHB programs, which are sometimes referred to as “maximizer” programs. To learn more about these programs and how they define specialty medications as non-EHBs, read Aimed Alliance's [non-EHB fact sheet](#).

Manufacturer copay assistance programs are for individuals with commercial insurance. A manufacturer copay assistance program can pay for some or all of an individual's cost-sharing for their medication. For example, if a health plan enrollee with a \$100 copay participates in a manufacturer copay assistance program, the program could contribute \$50 and the enrollee could pay the remaining \$50.⁴

Patient assistance programs can be used when an eligible individual is either underinsured or uninsured.⁵ These programs are typically run by charitable organizations but may also be run by the drug manufacturer of a particular medication. Eligibility requirements vary and can include diagnosis criteria, household income, family size, and medical expenses.⁶ Some charitable assistance programs provide a medication directly to the consumer, while others may provide some form of direct financial assistance.

Individuals enrolled in Medicare and Medicaid are not eligible for manufacturer copay assistance programs because use of these programs violates the federal Anti-Kickback Statute.⁷





CONSEQUENCES OF ALTERNATIVE FUNDING PROGRAMS

Delays in Access to Treatments

Alternative funding programs require a consumer's prescription to be passed through multiple parties before the consumer can access the medication. This process can result in a prescription being lost or ignored and result in patients experiencing delays in accessing their treatments. For some patients, these delays can cause patients to not receive their treatments on time, resulting in recurrence or progression of disease symptoms. This process also often imposes additional administrative and paperwork requirements for health care providers ultimately increasing their administrative burdens and costs.

Additionally, in some cases, if a consumer is denied by a patient assistance program, the alternative funding program may call their health care provider and request that a different medication be prescribed, so the alternative funding program can apply the patient to a different manufacturer's patient assistance program. Switching a patient's medication for the financial benefit of an alternative funding and not the patient's medical needs is an extremely dangerous form of non-medical switching that prioritizes profits over patients. To learn more, view Aimed Alliance's [non-medical switching resources](#).



Patient Assistance Programs

When alternative funding programs require consumers with health insurance coverage to enroll in financial assistance programs, they jeopardize the availability of these programs to support consumers who are genuinely in *financial need*. For example, charitable assistance programs are intended for individuals who are uninsured or underinsured, not for individuals who have adequate health insurance and are able to cover the cost of their medication but prefer not to do so. By exploiting such programs, alternative funding programs jeopardize the sustainability of important safety net programs intended for financially in-need consumers. As a result, charitable assistance programs may be forced to significantly reduce the number of consumers they can help. For consumers who rely on these programs, this could mean being forced to forego treatment due to unaffordability.

Copay Assistance Programs

When enrolled in an alternative funding program, the health plan accepts financial assistance on behalf of the enrollee but does not count the assistance toward meeting the enrollee's annual limit on cost-sharing. As a result, consumers may be required to unnecessarily pay thousands of dollars more to meet their annual cost-sharing requirements. Further, copay assistance is limited; it is subject to an annual cap. Once all available copay assistance is exhausted, it becomes increasingly difficult for enrollees to manage their copays, meet their deductibles, and reach their annual limits on cost-sharing. If a consumer is required to switch health plans mid-year but has exhausted all available copay assistance while enrolled in their previous plan, they will not be able to rely on copay assistance under the new plan for the remainder of the year.

International Importation

Alternative funding programs may require consumers to import their medications from outside the United States. However, federal law prohibits the importation of drugs that have not been approved by the U.S. Food and Drug Administration (FDA), including "foreign versions" of FDA-approved drugs.¹¹ Congress established this prohibition to help ensure that the domestic drug supply is safe and effective for consumers.¹² While importing unapproved prescription drugs is generally illegal, FDA's policy on importing prescription drugs for personal use recognizes that there may be circumstances in which the FDA may exercise enforcement discretion with respect to illegal importation.¹³ The types of personal importation that the FDA anticipated when it developed this policy are far from what occurs with alternative funding programs. The FDA intended this policy to apply to importation by individuals, not large health plans attempting to lower their prescription drug costs. Thus, importation of prescription drugs by alternative funding programs likely falls outside the scope of what FDA considers permissible conduct. If this practice is illegal, it raises questions about consumers' potential legal risks with respect to enrolling and participating in these programs. Regardless of legality, the practice also places consumers at risk of exposure to counterfeit, expired, or spoiled drugs.



HOW DO I KNOW IF MY HEALTH PLAN IS WORKING WITH AN ALTERNATIVE FUNDING PROGRAM?

If your employer has partnered with an alternative funding program, you may experience barriers in accessing your medication, or confusion as to how to navigate these programs. To find out whether your insurer may be working with an alternative funding program, ask yourself the following questions:



Did your health plan make you work with another company to access your medication?

After you attempt to fill a prescription at your pharmacy, often you will receive a letter from your health plan stating that the medication is only available if you work with their third-party specialty drug partner or program.

If your letter has this type of language, your health plan has likely partnered with an alternative funding program.



Did your health plan refuse to cover your medication because it was considered a non-essential health benefit or a covered non-essential health benefit?

If you attempted to fill your prescription but received a denial letter stating the medication is considered a “covered non-essential health benefit” or a “non-essential health benefit,” you may be enrolled in an alternative funding program. As a result of this designation, your denial letter may also state that you need to work with a third-party to access your medication.

Many health plans define a substantial amount of specialty drugs as “non-essential health benefits” (non-EHBs) so that the plan can accept copay assistance and consumer cost-sharing without counting it towards the annual limit on cost-sharing (an important protection created by the Patient Protection and Affordable Care Act (ACA)). This non-EHB designation is also strategically employed to encourage hesitant individuals to enroll in the third-party program or be responsible for substantial and unreasonable coinsurance payments.





Did your health plan tell you the medication is a benefit exclusion, or your medication was carved out from coverage?

If you attempted to fill your prescription but received a denial letter stating the medication is considered an “excluded benefit,” you may be enrolled in an alternative funding program. As a result of this designation, your denial letter may also state that you need to work with a third-party to access your medication.



Did your health plan state that the coverage decision cannot be appealed?

If you attempted to fill your prescription but received a denial letter stating the medication is considered an “excluded benefit,” “non-EHB,” or otherwise not covered by the plan, and you cannot appeal the decision or access the medication through a prior authorization process, you may be enrolled in an alternative funding program.

Some health plans have begun denying coverage and refusing to allow consumers to appeal the decision to fast-track the consumer’s application to the patient assistance program. As explained below, this may violate federal law.



Did your health plan state that if you refused to work with the third-party program, you would be responsible for 100 percent of the cost of your prescription drug, and it would not count towards your annual cost-sharing requirements?

If you tried to avoid working with a third-party program, and your health plan told you that if you chose not to work with program you would be responsible for 100 percent the cost of the drug, you may be enrolled in an alternative funding program. This tactic is used by alternative funding programs to steer patients to the program and coerce hesitant consumers into the program.

Health plans categorize specialty medications as non-EHBs so the plan can claim that a consumer could be responsible for 100 percent the cost of the medication, and it would not count towards their annual limits on cost-sharing if they did not work with the alternative funding program. Understandably, it is often not financially feasible for a consumer to pay 100 percent of the cost of the medication indefinitely. As a result, consumers feel compelled to go through the alternative funding program and apply to the patient assistance programs.



Did your health plan request information about your condition, household income, or household size to apply to a patient assistance program?

If you attempted to fill your prescription but were contacted by a third-party requesting information about your health condition, annual household income, or household size, you may be enrolled in an alternative funding program.

PAPs are only available to eligible consumers. To be considered an eligible consumer, you must be uninsured or underinsured, and have a certain income, health condition, and household size to qualify. Therefore, an alternative funding program needs this information from you to submit your application to the PAP.

You may also be asked to sign something attesting that you do not have health insurance coverage for your drug. Again, this is required by many PAPs to ensure only uninsured or underinsured individuals are using their programs.



Did your health plan cover your prescription drug once the patient assistance program stated that you did not qualify for the manufacturer's "free drug" program?

Many health plans that work with alternative funding programs have language within their plan benefits stating that if you are denied from a PAP the plan will cover the medication like a typical pharmacy benefit. If your plan agrees to cover your medication after being denied by a PAP, you may be enrolled in an alternative funding program.



Did your health plan tell you that you had to work with a third-party company to import your prescription drugs from Canada or another country?

In some cases, if you are not eligible for the PAP or the manufacturer copay assistance program, the third-party company will try to import your medication from outside the United States. In other cases, you may be asked to import your medication from outside the United States even before you apply to a PAP or copay assistance program. If you are being asked to import your medication from Canada or another country, you may be enrolled in an alternative funding program.





MY HEALTH PLAN IS REQUIRING ME TO WORK WITH AN ALTERNATIVE FUNDING PROGRAM. WHAT CAN I DO?

Review your plan documents.

As soon as you think you are enrolled in an alternative funding program, you should review your plan documents to determine what information your plan provides about the alternative funding program. Look for specific information regarding whether the alternative funding program requires you to apply to a PAP or copay assistance program, and if it uses any international importation programs. Alternative funding programs may use one or all of these tactics.

You should also look for any information your health plan provides regarding your cost-sharing requirements if you chose not to work with the alternative funding program or if you are not eligible for the alternative funding program sources (e.g., what happens if you are denied by the PAP?).

Speak with your employer about your concerns.

Employers implementing alternative funding programs were likely told by alternative funding programs that these programs would help lower employer spending on specialty drugs and **would not** interfere with their employees' ability to access their medications.

Your employer may not be aware of the challenges experienced by employees who are subject to these programs. Therefore, if you are experiencing challenges with these programs, speak with your employer about what other options may be available.



Appeal the benefit denial.

Typically, when you are enrolled in an alternative funding program, your health plan will immediately deny your request for coverage of your specialty medication. When the health plan sends you this denial, often at the same time, it will refer you to the alternative funding program.

However, when you receive this first denial from your health plan, you have a right to appeal this adverse benefit decision before beginning to work with the alternative funding program.

There are two types of appeals you can file: (1) an internal appeal, or (2) an external appeal.



Internal Appeals

The first type of appeal is an internal appeal.¹⁴ This means you can ask your insurer to conduct a full and fair review of its decision. To appeal the denial, you should do the following:



Review the determination letter. Your insurer should have sent you a determination letter to tell you that it would not cover your medication. Review this document so you can understand why your insurer denied coverage and how you can appeal the denial.



Collect information. Collect the determination letter and all other documents the insurance company sent you. This includes your insurance policy and your insurer's medical necessity criteria. "Medical necessity criteria" refers to your insurer's policy for determining whether a treatment or service is necessary for your condition.¹⁵



Request documents. If you did not receive the determination letter or do not have your policy information, the medical necessity criteria, or the instructions and forms for filing an appeal, call the insurer's customer service representative and ask for these documents. The company website should provide a toll-free telephone number to call.



Call your health care professional's office.

Your health care professional's office or clinic may have people on staff to help with the appeals process. If so, they might tell you how to fill out the forms to request an appeal, write an appeal letter on your behalf, or handle the appeal request for you.



Submit the appeal request.

It is important for you or your health care professional's office to submit the appeal as soon as possible, along with any letter from the health care professional and all additional information the insurer requires.



Once you file an appeal, expect to wait up to 30 days to hear back from the insurance company. It could take up to 60 days for a response if you already received the treatment and are waiting for reimbursement.



Follow up. Follow up with your insurer regularly until you hear back. Be sure to keep a record of the name of any representative you speak with about the appeal, the date and time you spoke with that person, a confirmation number for the call, and a summary of your discussion.



What if my treatment has recently been approved by the Food and Drug Administration and my insurer has denied coverage because it considers the treatment experimental?

You should ask your insurer for a written statement of the exact reasons for the denial (i.e., why the treatment is considered experimental), if that information has not already been provided. Review your plan documents carefully to see how the plan defines “experimental” (or “investigational” or “unproven”). These terms can vary among plans.

In general, an insurer may deem a treatment experimental if it determines that the treatment is not the standard of care for a particular condition.¹⁶ Experimental treatments may include non-FDA-approved treatments, those that lack substantial evidence to support their medical effectiveness, and off-label treatments.¹⁷ The FDA will only approve a treatment if there is evidence that the treatment is safe and effective. Therefore, if your treatment has recently been approved by the FDA and is indicated for your condition, then you may be able to appeal the denial on the basis that it is no longer “experimental.”

If you are being prescribed an FDA-approved treatment off label (i.e., it is not indicated for your condition), review your plan documents closely. Some plans have exceptions for coverage of FDA-approved off-label treatments for rare disorders if certain requirements are met.¹⁸

External Appeal/Review

If your health plan denies your internal appeal, you are entitled to take your appeal to an independent third party for an “external review,” which means the insurance company no longer gets the final say over whether to approve a treatment or pay a claim. The situation applies if the insurer denies your appeal or if your medical situation is urgent and waiting would jeopardize your life or ability to function.

To trigger an external review, file a written request with the independent organization within 60 days of the date your insurer sent you a final decision. The process should take no more than 60 days. However, in urgent situations requiring an expedited review, the process should take no longer than four business days. To find out whom to contact in your state to request an external review, visit www.CoverageRights.org.

Plan Term Compliance

In some cases, your health plan may state that the original decision to deny coverage is not appealable and cannot be reviewed. Similarly, some health plans may allege that the decision is not appealable because you must comply with the plan terms, which require you to work with the alternative funding program. In these cases, it may be beneficial to immediately request an external appeal of the plan terms and your request for coverage. However, you **must** ensure that any appeal application you submit clearly states that you are requesting a medical necessity exception to ensure the reviewer evaluates the clinical criteria and exception requirements properly.



Notify your health plan and the alternative funding program as soon as you receive a denial letter from the PAP.

If you already started working with the alternative funding program and applied to a PAP but received a denial letter, immediately notify both your alternative funding program and health plan that you were denied. If you do not immediately notify both the plan and the alternative funding program, your medication could get lost in the administrative back-and-forth between the PAP, alternative funding program, and plan. For you, this may mean additional delays in accessing your medication.

Once you have notified your plan that you were denied by the PAP, the method for accessing your medication will vary depending on the specific type of alternative funding program you are working with.

Some plans will automatically cover the medication as a typical pharmacy benefit, subject to the plan's standard cost-sharing requirements. Under other plans, the medication will still not be covered by the plan. If you are denied by a PAP and your plan still refuses to cover your medication, you should file a medical necessity exception request with your plan. Under federal law, health plans are required to provide an avenue for consumers to access a non-formulary treatment when the medication is deemed medically necessary. Under this law, if your medication is deemed medically necessary, the plan is required to cover the medication, although there may be high cost-sharing requirements.

To help consumers facilitate these conversations with plans and alternative funding programs, Aimed Alliance drafted the examples below to help consumers initiate these conversations. This is not legal advice.

Denied by PAP, but health plan terms state if denied, the medication will be covered by the plan.

Dear [health plan and alternative funding program]:

I have been enrolled with the alternative funding program, [add program name]. Per the program's mandated process, I applied to the manufacturer patient assistance program (PAP) to try and access my medication. On [date], I received notification that I was denied by the PAP.

Therefore, because I am not eligible for the PAP, the health plan is required to cover the cost of my medication per the plan's terms and conditions [cite section of health plan that discusses this if you know it].

I need immediate access to this medication, as this medication [if you are comfortable, explain how this medication helps you stay healthy, work, care for family, etc.]

Please contact me at [add best contact information] if you need any additional information from me.

Thank you,
[Add Name]



Denied by PAP and health plan still refuses to cover the cost of the medication.

Dear [health plan and alternative funding program]:

I have been enrolled with the alternative funding program, [add program name]. Per the program's mandated process, I applied to the manufacturer patient assistance program (PAP) to try and access my medication. On [date], I received notification that I was denied by the PAP.

Currently, [name health plan] is still refusing to cover the medication. Therefore, I am writing to file an exception request to access my medically necessary treatment.

Under 45 CFR § 156.22(c), a "health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135."

The health plan must respond within 72 hours and if the medication is deemed medically necessary, the plan is required to cover the prescription for the duration of the plan year, including refills.¹⁹

You will be receiving additional information from my health care provider soon. Contact me at [add best contact information] if you need any additional information from me.

Thank you,
[add name]

If you are filing a medical necessity exception request, make sure you submit appropriate documentation from your health care provider explaining why this medication is medically necessary. You should also include specific language in your letter stating that you want the plan to review its decision and determine if your request for medication meets the plan's definition of "medical necessity." This language will help ensure your health plan appropriately reviews the appeal under a medical necessity standard and not whether the medication is a covered on the plan's formulary.

If your health plan denies your request for an exception, you can file an external appeal as described above.

The alternative funding program is telling me that I can get my medication from a foreign country. What should I do?

Given the health risks of importing your medication from a foreign country, contact your health plan and inform them that federal law prohibits them from requiring you to import your medication from a foreign country. You can also share [Aimed Alliance's 2023 Letter](#) to FDA regarding alternative funding programs and how mandated importation violates federal law, as well as the [FDA's response](#).



OPEN ENROLLMENT & ADVOCACY

I am currently selecting a new health plan and trying to determine if a plan uses an alternative funding program. What language should I look for to determine if the plan uses an alternative funding program?

Unfortunately, there is not one single term that is used to describe alternative funding programs. However, examples of language may include the following statements:

- Your health plan is working with a third party to manage specialty medications;
- Some prescription drugs are either “covered non-essential health benefits” or simply “non-essential health benefits;”
- If you choose not to enroll in the alternative funding program, you will be responsible for a coinsurance between 30 to 100 percent and it will not count towards your annual limits on cost-sharing; and
- Requirements that you disclose personal financial information to a third party company to apply for PAP or copay assistance.

Whom do I contact if I am struggling to work with an alternative funding program and my employer is not willing to help?

If you are struggling to understand the alternative funding program your health plan is working with, you can contact Aimerd Alliance at policy@aimedalliance.org. Aimerd Alliance does not provide legal representation but can help you identify resources, information, and tools that can help you navigate this process.

I was able to access my medication, but I want to help raise awareness about the challenges I experienced with an alternative funding program. Whom should I contact?

If you are interested in sharing your story and experience working with an alternative funding program, please contact Aimerd Alliance at policy@aimedalliance.org. We value hearing about your experience and will not share any of your personal information or experience without your permission. We understand that this is your story, and you should always have the final decision on how and when your story is shared.

WHERE CAN YOU GET MORE INFORMATION?

Please contact Aimerd Alliance
1455 Pennsylvania Ave, NW, Suite 400, Washington, DC 20004
(202) 349-4089 • policy@aimedalliance.org



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