

COST-SHARE ASSISTANCE

FREE THE FUNDS



WHAT IS COST-SHARE ASSISTANCE?

Health care innovations made possible by biologic therapies, and new uses for IVIG, have improved the lives of thousands of patients living with chronic diseases and complex immune disorders. Unfortunately, these new therapies can be incredibly expensive. As a result, many patients are unable to access these treatments, despite desperately needing them to manage debilitating illness.

To provide relief and increase access to these medications, many manufacturers have created assistance programs to help patients manage the financial burden by covering a portion of the patient's cost-share.

THAT SOUNDS GREAT, BUT WHAT'S THE ISSUE?

Cost-share assistance programs *can* be used to incentivize prescribing habits. For example, in order to encourage patients and physicians to select a more expensive brand-name drug over the generic, the manufacturer might offer a coupon to share a patient's cost for their brand-name drug. Though the coupon might reduce the cost to the patient, the health plan would still pay full price for the brand-name drug.

In order to prevent excessive government spending, the Federal Anti-Kickback Statute prohibits pharmaceutical manufacturers from providing cost-share assistance to beneficiaries of government-subsidized health plans, when less expensive, equally effective alternatives are available.* So, while patients with commercial health plans are eligible to receive financial relief from these programs, patients on government-funded plans are not.

PATIENT A
HAS COMMERCIAL COVERAGE



✓ WITH COST-SHARE ASSISTANCE



✗ WITHOUT COST-SHARE ASSISTANCE

PATIENT B
HAS MEDICARE COVERAGE

*Generally, NICA agrees that this protection is duly warranted, but in the case of infusion patients, a lack of clarity within the statute is doing more harm than good.



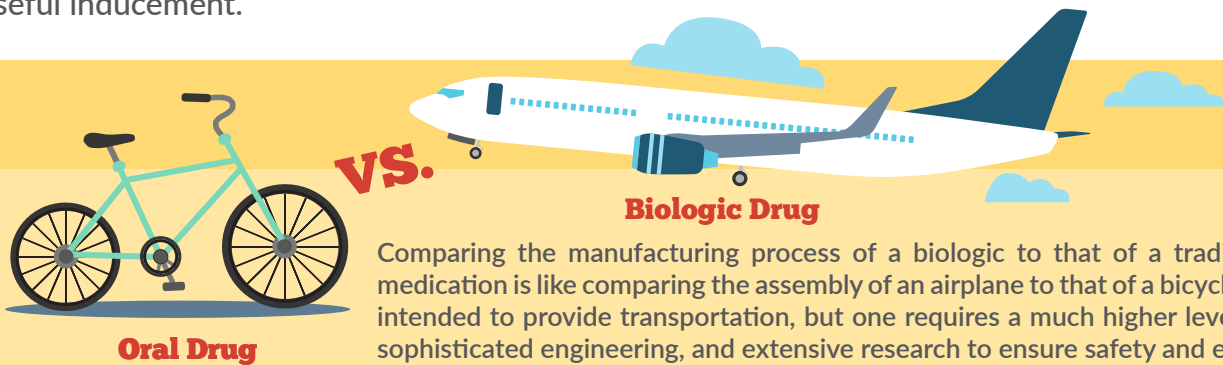
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THERE ARE NO GENERIC BIOLOGICS

Conventional medications are created using a chemical formula, so, using the original recipe, other companies can create generic drugs which act exactly like the original. Biologics, however, are much more complex medications, which are made in living cells. This high level of complexity makes it impossible to create a “generic” version of biologics.

Biologics are typically prescribed when a patient has exhausted every other option. Because there are no less expensive, equally effective alternatives, providing cost-share assistance to patients requiring these treatments should not be considered an excess cost to a Federal program, nor should it be considered a purposeful inducement.



Comparing the manufacturing process of a biologic to that of a traditional oral medication is like comparing the assembly of an airplane to that of a bicycle. Both are intended to provide transportation, but one requires a much higher level of detail, sophisticated engineering, and extensive research to ensure safety and efficacy.

SO, WHAT IS THE SOLUTION?

THE ANSWER IS SIMPLER THAN YOU MIGHT EXPECT!

NICA has requested that the Office of Inspector General (OIG) issue new guidance, clarifying whether manufacturer cost-share assistance programs for biologics, IVIG, and other specialty medications paid for by federal health plans are considered a violation of the federal anti-kickback statute, given that there are no less expensive, equally effective alternatives for these medications. A statement of safe harbor would allow pharmaceutical manufacturers to make these funds available to thousands of vulnerable patients who struggle with the high cost of the medications they so desperately need.

To view and sign NICA's petition asking the OIG to clarify this language and make manufacturer cost-share assistance funds available to patients living with chronic diseases and immune disorders, who are covered by Federal health plans, visit infusioncenter.org/freethefunds.

National Infusion Center Association is a 501(c)3 non-profit organization founded to increase access to office-administered IV/injectable medications. To learn more about NICA and our ongoing advocacy and educational initiatives, please visit us at infusioncenter.org.