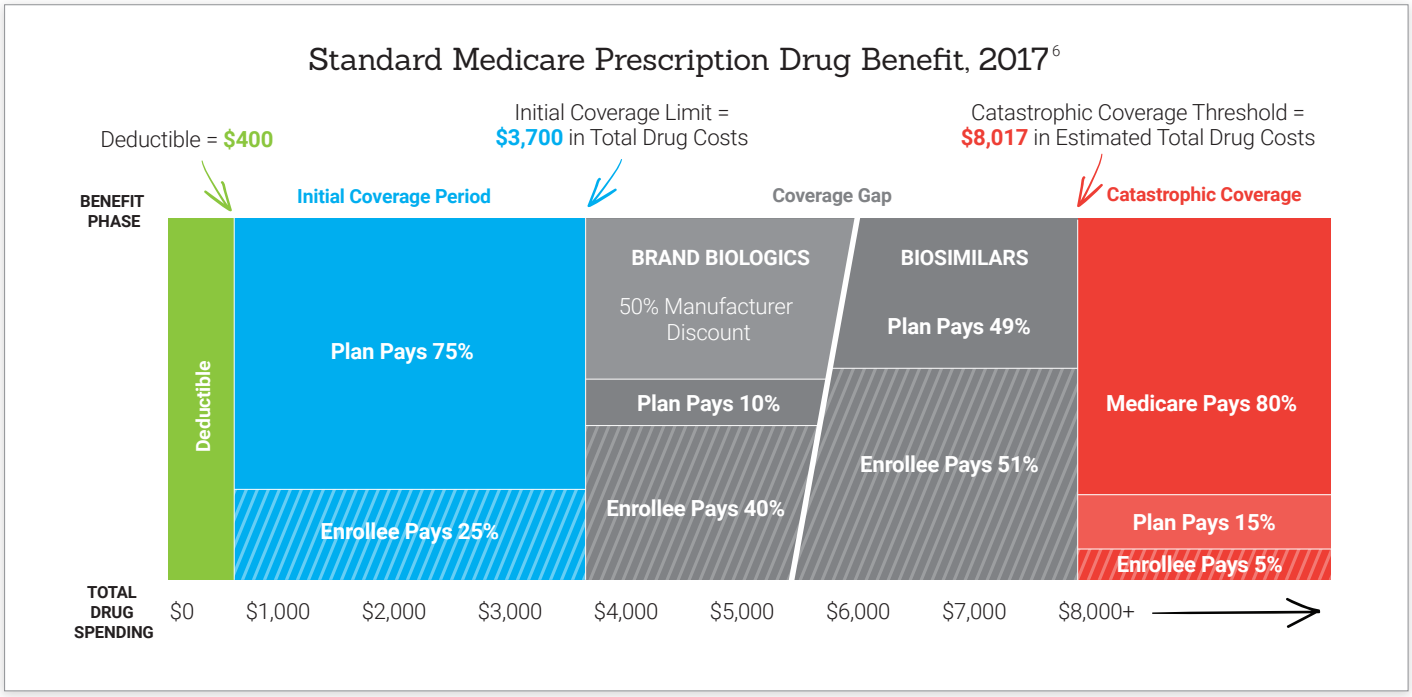
Increasing Patient Access to Biosimilars in Medicare Part D

Biosimilar medicines are safe, effective and affordable versions of costly brand biologics for the treatment of cancer, rheumatoid arthritis and other complex diseases. Biosimilars are widely viewed as the next frontier for affordable medicines. By the year 2025, more than 70 percent of drug approvals are expected to be biological products.[1] Experts estimate that biosimilars could save between $44 billion and $250 billion over the next 10 years.[2]

Biosimilars present a significant opportunity for patient and program savings in the Medicare Part D program. However, under current law, patients in the Part D coverage gap face significant barriers to access for biosimilar options, and may actually be forced into using higher priced biologics. **Congress should treat biosimilars and brand biologics equally within the Coverage Gap Discount program, so that patients will not be forced into paying for higher-cost treatments.**

Background

The standard Medicare Part D benefit is divided into four phases of coverage: deductible, initial coverage, coverage gap and catastrophic coverage. Once in the gap, patients have greater out-of-pocket exposure, up to 40 percent for brand-name drugs and 51 percent for generics.[3] By 2020, all patients will face 25 percent exposure in both the initial coverage phase and coverage gap.[4] Once a patient reaches a "True Out-of-Pocket" (TrOOP) spend of $4,950, he or she enters the catastrophic phase of coverage where a patient has exposure to no more than 5 percent of costs, the Part D plan is responsible for 15 percent of the cost and Medicare pays the other 80 percent.[5]



To limit patient out-of-pocket costs, Congress created the Coverage Gap Discount Program, which required brand name manufacturers to provide 50 percent discounts to patients while in the coverage gap.[7] Those 50 percent discounts are also used in the calculation of TrOOP, along with beneficiary contributions. Biosimilar manufacturers are not eligible to pay those discounts, leaving patients and Part D plans to pick up the cost differential.

The Problem

The structure of the Coverage Gap Discount Program unintentionally creates a significant barrier for patient use of lower-cost biosimilars in the Part D program, instead forcing consumers to use higher-cost brand biologics.

1. **Part D Plan Sponsors Are Incentivized to Place Patients on Higher-Cost Brand Biologics**

   - » Because discounts provided by brand biologics are included in the calculation of TrOOP, plans are encouraged to place patients on a higher-priced brand biologic that will move patients through the coverage gap and into catastrophic coverage faster and with lower out-of-pocket costs compared to a lower-cost biosimilar that cannot provide a 50 percent discount that counts toward TrOOP.

   - » This approach creates significant barriers for manufacturers who wish to pursue developing biosimilars that would be covered by Medicare Part D, as it would be effectively impossible to ever offer sufficient discounts to be included on formularies. Without being able to obtain coverage, manufacturers will pursue other markets.

2. **Patients Face Higher Out-of-Pocket Costs for Lower-Cost Biosimilars**

   - » Without the ability to "credit" the brand discount toward TrOOP, patients pay more out of pocket for a lower-cost biosimilar than they would for a brand before reaching the catastrophic coverage level.

   - » While patients will move to catastrophic coverage faster by using high-priced brand products, the 5 percent cost share that applies once in the catastrophic phase will also be significantly higher than if the patient were given a biosimilar. For many brand biologics, which can cost thousands of dollars per treatment, this is a significant financial burden. Ultimately, patients, payers and Medicare all pay more for brand biologics than they would if the Coverage Gap Discount program were amended to include biosimilars.

The Solution

Congress should amend the Part D coverage gap discount program to classify biosimilars as "applicable drugs" in the Coverage Gap Discount Program. This change would allow biosimilar manufacturers to pay the 50 percent discounts paid by their brand competitors, and participate on a level playing field to compete for placement on Part D plans' formularies. **It would reduce both patient out-of-pocket costs and Part D program spending.**

References

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7. GAO, "Medicare Part D Coverage Gap," September 2012 (link).