THIRD WAY

MEMO *Published August 15, 2016 • 3 minute read*

Developing a Value-based Approach to Pay for Biosimilars

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One of the promising areas for reducing the cost of prescription drugs is the development of biosimilars. This new type of drug can come on the market after a patent and other legal protections for an original biologic drug have expired. The Food and Drug Administration (FDA) has already approved two biosimilars, and now is the time to determine the best way for Medicare to reimburse for them in order to get their full benefit. The Centers for Medicare and Medicaid Services (CMS) has made an attempt to do this, but the specific strategy it has chosen would undermine the potential for a robust biosimilar market. Congress should pursue a course correction.

This memo identifies the key weakness of the CMS strategy on biosimilars and a path toward long-term solution.

Biosimilar Reimbursement

Biologic drugs are complex, cost hundreds of millions of dollars to create, and tackle some of the biggest medical problems in the world—from rheumatoid arthritis to breast cancer. Biosimilars are often thought of like generics—they

come on the market after a patent and other legal protections for an original biologic have expired. But, unlike generics, they are not identical but highly similar to the product and may not serve the full set of clinical uses (also called indications) as the original brand name biologic product. Biosimilar manufacturers face significantly higher costs to get approval for the full set of uses as the original biologic or to seek the designation of "interchangeability" from the FDA, which denotes products that can be substituted for one another. Therefore, biosimilar manufacturers may not seek Food and Drug Administration approval for all of the same uses as the original.

The CMS rule on biosimilar reimbursement does not account for such product variation. In its final rule on reimbursing for biosimilars, it would lump all biosimilars into one reimbursement code and reimburse them all at a blended payment rate regardless of whether or not they were approved for all of the same indications. The effect of this reimbursement system will be a less robust and dynamic biosimilar market. Here is one way this could happen: a manufacturer could invest a lot of money to develop a biosimilar that has as many uses as the original biologic, or it could invest less money on a biosimilar that has fewer uses. Under the CMS rule, both manufacturers would receive the same reimbursement. The rule would push manufacturers into a race to the bottom.

The Path Forward

Congress should suspend this CMS rule, and CMS should reissue a policy to allow for the development of a robust biosimilar market and a better reimbursement system which is consistent with the direction for the rest of Medicare payment policy. In the meantime, Congress should provide for the use of unique codes and payments for each biosimilar.

The question of what would be a better reimbursement model is not clear. However, one approach could emerge out of the already-enacted provider payment reform known as MACRA. This reform will move Medicare away from the "buy and bill"

payment system in Part B, where providers purchase drugs and Medicare reimburses them based on the average sales price. Instead, providers using the alternative payment models under MACRA will be accountable for the total cost of care for a given set of services and will have an incentive to seek the drug with the best value that effectively addresses a patient's condition. This new incentive for providers to seek greater value from health care services and products is similar to health plans' incentives to seek greater value from drugs under the successful Part D program, which covers drugs that patients get through a pharmacy.

The MACRA approach could yield more economically efficient Part B payments for biosimilars, but only if CMS develops it in conjunction with the goal of creating a strong biosimilars market. The current CMS policy on payments and coding discourages that market while a reissued policy on biosimilars could take advantage of the new incentives under MACRA to give patients the treatments that achieve the best outcomes at the lowest cost.

TOPICS

HEALTH CARE COSTS 51