



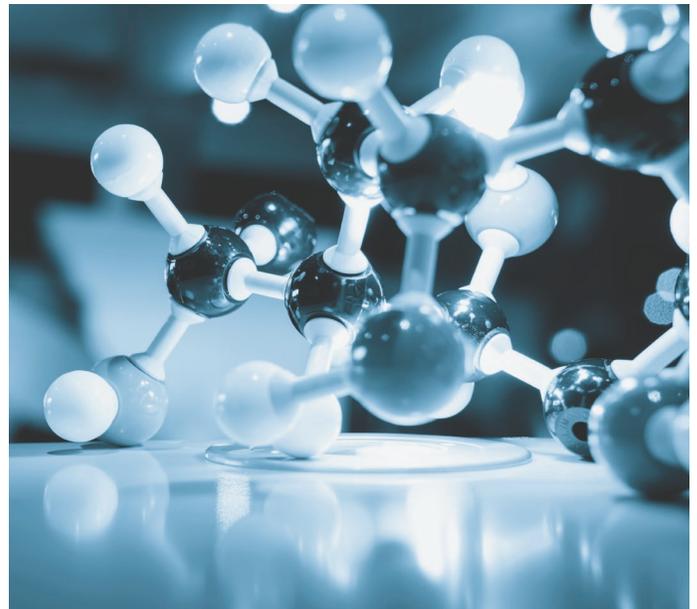
Biosimilars: *Innovatix Supports the CMS' Reimbursement Policy*

The Issue

In October 2015, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that includes language for how biosimilar biological products (biosimilars) will be reimbursed. The CMS decided to base the payment amount for biosimilars on the average sales price of all biosimilar products included within the same billing and payment J code. Innovatix supports the CMS' decision because it will help lower costs, increase competition in the marketplace, and improve patient access to necessary treatments.

Background

The Biologics Price Competition and Innovation Act (BPCI Act) of 2009 was signed into law under the Patient Protection and Affordable Care Act in March 2010. The BPCI Act created an abbreviated approval pathway for biological products that are demonstrated to be highly similar (i.e., biosimilar) to a United States Food and Drug Administration (FDA) approved biological product (known as a reference or innovator product). The biosimilar must be found to have no clinically meaningful differences in terms of safety, purity, and potency. The Medicare reimbursement policy to include all biosimilars for the same reference product as part of the same J code will reward manufacturers of the lowest-priced biosimilar with a higher volume in the marketplace. As a result, biosimilars will increase patient access to critical treatments and generate savings to the overall healthcare system.



Our Position

Innovatix applauds the CMS for including all biosimilars for the same reference product in the same J code. The CMS reimbursement decision will encourage manufacturers to enter the market and be included in the same J code as other biosimilar manufacturers for the same reference product. This will create a more robust and competitive market. The CMS should continue to explore ways to lower costs through increased competition and innovation in the biologic marketplace, thereby increasing patient access to cutting edge therapies and treatments for beneficiaries.