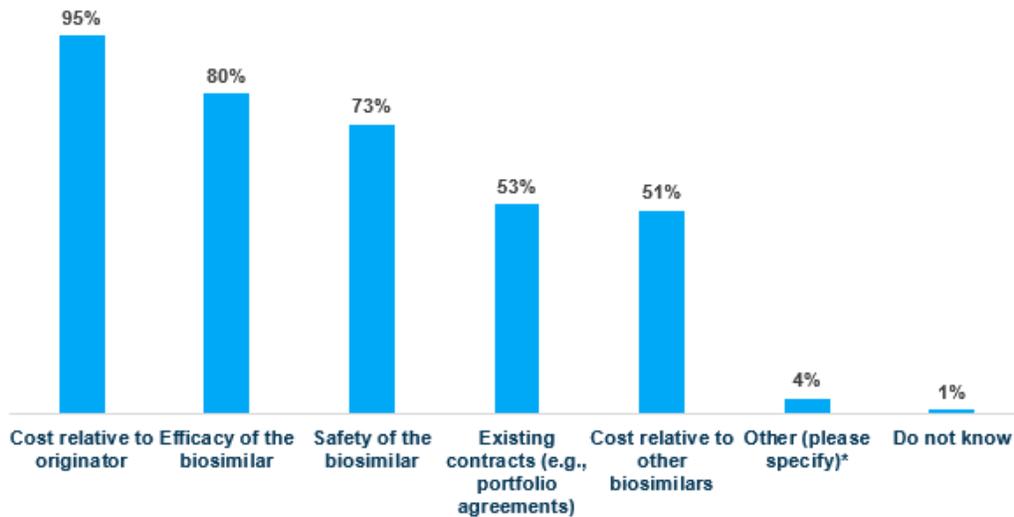


BIOSIMILARS GAIN WIDESPREAD ADOPTION BY HEALTH PLANS

New research from Avalere finds that most health plans are covering at least one of the two biosimilar products currently on the market. Based on a national survey of health insurers, 81 percent of plans report they are covering a biosimilar product. Nearly all payers indicate that a biosimilar’s cost relative to the originator is a key decision-making factor for determining coverage. In addition to costs compared to the originator, health insurers cite efficacy and safety of the biosimilar as important factors for coverage decisions (see Figure 1).

In 2010, a biosimilar approval pathway was created with an expectation that it would spur competition among biologics and could offer savings for the U.S. health system. Since then, the Food and Drug Administration (FDA) has approved five biosimilars, two of which have launched: Zarxio® (filgrastim-sndz) and Inflectra® (infliximab-dyyb). Zarxio® and Inflectra® were approved as biosimilars with all the available indications of their reference products. Neither product sought an FDA designation of interchangeability.

Figure 1. Key Elements for Determining Coverage

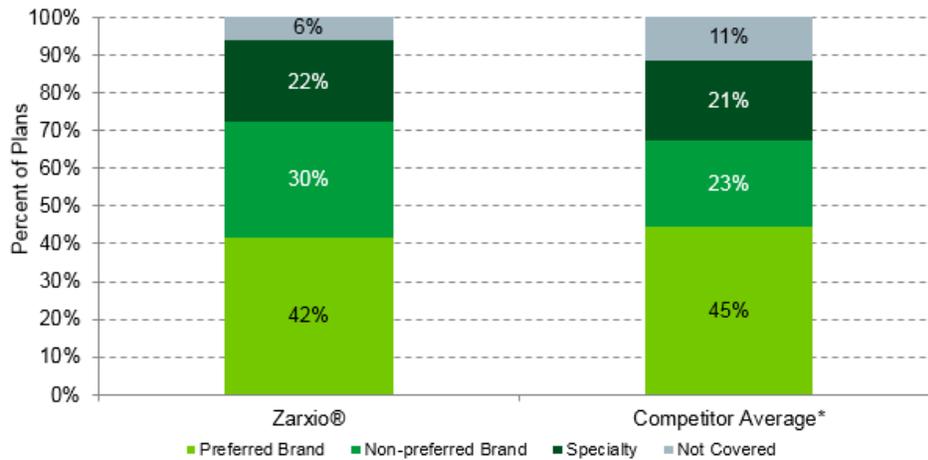


Source: Avalere Policy 360. *Biosimilars: U.S. Payer Perspective*. June 2017.

To supplement the survey findings, Avalere experts reviewed how insurance plans cover Zarxio® and Inflectra®. Nearly two years after its launch, Zarxio® is covered by 94 percent of employer-sponsored insurance plans (see Figure 2). Over 40 percent of employer plans cover Zarxio® in the preferred brand tier, which is in line with the average of its competitors. Placement on the preferred brand tier results in lower out-of-pocket costs for patients compared to drugs on non-preferred brand or specialty tiers.



Figure 2. Zarxio® Tier Placement in Employer-Sponsored Insurance Plans, 2017



*Competitors include Granix®, Neulasta®, and Neupogen®.

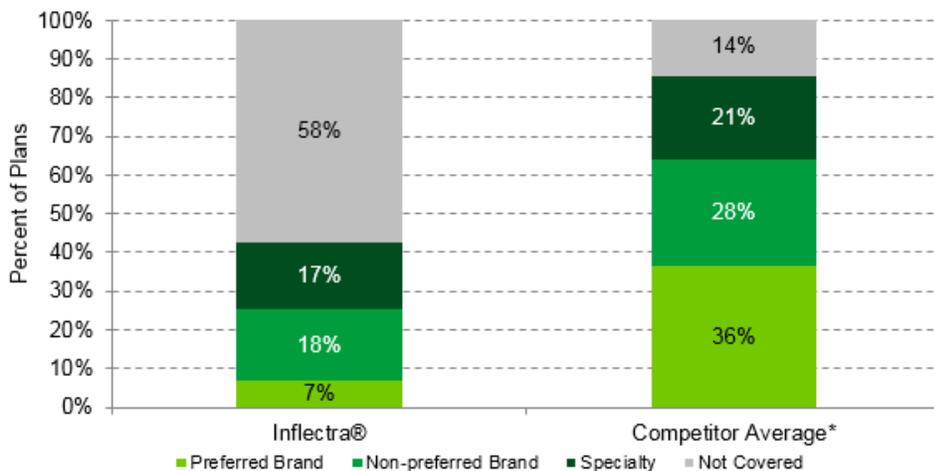
Note: Coverage is weighted according to unique plan-state combinations. Sample includes all plans offered in 50 states and the District of Columbia. MMIT uses universal tier status rather than raw tier to facilitate comparisons across plans and markets.

Source: Avalere Health PlanScape®, June 2017. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

“Payers are placing Zarxio® in preferred brand tiers, which suggests they are increasingly comfortable with biosimilars once they become familiar with them,” said Gillian Woollett, senior vice president at Avalere. “It also suggests uptake of biosimilars by payers may not depend on biosimilars receiving interchangeability status from FDA.”

A review of insurance plans’ formularies shows that the market for Inflectra® is still developing. After seven months on the market, 42 percent of employer plans are covering Inflectra® (see Figure 3).

Figure 3. Inflectra® Tier Placement in Employer-Sponsored Insurance Plans, 2017



*Competitors include Cimzia®, Enbrel®, Humira®, Orenicia®, Remicade®, Simponi®, and Xeljanz®.

Note: Coverage is weighted according to unique plan-state combinations. Sample includes all plans offered in 50 states and the District of Columbia. MMIT uses universal tier status rather than raw tier to facilitate comparisons across plans and markets.

Source: Avalere Health PlanScape®, June 2017. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.



As of February 2017 (latest available data), 64 programs were enrolled in the FDA's Biosimilar Products Development Program, and the Agency has received meeting requests to discuss the development of biosimilars for 23 different reference products¹. So far, manufacturers have publicly disclosed the submission of 14 biosimilar applications to the FDA (including those already approved).

“Biosimilars were intended to increase competition among biologics and potentially reduce drug costs, but the biosimilars market has been slow to develop in the U.S.,” said Tom Kraus, senior vice president at Avalere. “The growth of the biosimilar market will be measured as policy, market, and intellectual property related challenges continue to be addressed.”

There are several obstacles to biosimilar market growth, including the complexity of biosimilar development, uncertain provider and patient acceptance, and intellectual property rights. One such barrier was recently addressed with the recent Supreme Court decision that will allow a biosimilar to launch sooner than 180 days after approval. Continuing to overcome these barriers will be key to creating a robust biosimilars market.

For Policy 360 Members Only: [Read Avalere's Full Analysis](#)

Methodology

Avalere surveyed U.S.-based health plans between April 11, 2017 and May 1, 2017 using an online platform for collecting survey response. Respondents were recruited from a panel of health plan personnel and then screened to determine eligibility to participate, requiring that they be a medical director, pharmacy director or have a similar role. They were also required to be a decision maker or influencer in their health plan. A total of 50 qualified representatives participated in the survey, representing 45 different health plans. Health plans included in the study represent 183 million of the covered lives in the United States. Full methodology is available in the report.

Formulary data is from Managed Markets Insight & Technology, LLC, an Avalere partner that maintains comprehensive formulary data across a range of payer channels, including the exchanges, Part D, and employer markets. Formulary coverage is based on a drug's listing on the plan's published formulary in MMIT's database. MMIT gathers data directly from health plans and pharmacy benefit managers, ensuring the accuracy and validity of the formulary data. MMIT's pharmacists and clinicians interpret and standardize formularies. In addition, MMIT researchers engage with issuers to understand formulary characteristics, including processes around open and closed formularies, and to understand how plans make coverage decisions so that data reflects accurate consumer experiences for obtaining medications. Formulary data is based on coverage in all 50 states and DC as of June 2017; note that formularies may change throughout the year.

###

Avalere Health, an Inovalon Company, is a strategic advisory company whose core purpose is to create innovative solutions to complex healthcare problems. Based in Washington, D.C., the firm delivers actionable insights, product solutions and custom analytics for leaders in healthcare business and policy. Avalere's experts span 230 staff drawn from Fortune 500 healthcare

¹Janet Woodcock, M.D., testimony before the Committee on Health, Education, Labor and Pensions, U.S. Senate, on March 21, 2017.



companies, the federal government (e.g., CMS, OMB, CBO and the Congress), top consultancies and nonprofits. The firm offers deep substance on the full range of healthcare business issues affecting the Fortune 500 healthcare companies. Avalere's focus on strategy is supported by a rigorous, in-house analytic research group that uses public and private data to generate quantitative insight. Through events, publications and interactive programs, Avalere insights are accessible to a broad range of customers. For more information, visit avalere.com, or follow us on Twitter @avalerehealth.

