Biosimilars Forum Submission of New and Updated Research

On July 13, 2017, the Centers for Medicare and Medicaid Services (CMS) published the CY 2018 Proposed Rule for the Medicare Physician Fee Schedule (MPFS). The Proposed Rule included a solicitation for public comment on the effects of CMS' biosimilar payment policy. Specifically, CMS solicited new or updated information regarding biosimilar reimbursement.

Below is a sampling of new data and information provided to CMS by the Biosimilars Forum and its members as part of their response to the MPFS comment solicitation.

Budgetary Impact Research: **Unique Coding and Reimbursement Could Achieve Significant Savings**

- Xcenda, working with the Biosimilars Forum, modeled alternative payment methodologies using updated economic data. While CMS' policy is estimated to offer $49.9 billion in savings to the Medicare program over 10 years, an alternative coding policy, which would provide each biosimilar with its own billing code and separate payment rate, could increase savings by an additional $15.1 billion, or 30% ($65.0 billion in total over 10 years). The additional savings are generated primarily through the potential for increased biosimilar availability, long-term price competition among manufacturers of biosimilar products and reference products, and higher rates of utilization over time.

- A forthcoming report from the RAND Corporation, a nonprofit research organization, "estimates that biosimilars will lead to $54 billion reduction in direct spending on biologic drugs from 2018-2027, or about 3% of total estimated biologic spending over the same period, with a range of $25 to $150 billion." The actual savings hinge on a variety of factors, including regulatory and policy decisions that shape the biosimilar market.

Payer Studies: Blended Coding Impact on Adverse Event Tracking

- CMS requires each claim for payment for a biosimilar product to include a modifier identifying the product's manufacturer. Outside of Medicare, according to a recent payer study conducted by Xcenda, 65 percent of payer respondents do not require the use of a randomly assigned modifier code to specify the manufacturer for claims of biosimilars. Further, among payers that do require use of modifiers, these modifiers are applied inconsistently -- 64 percent of survey respondents noted that they rarely require the use of modifiers above and beyond Medicare requirements.

- This data is supported by a separate study performed by Avalere, which analyzed the use of modifiers across Medicare and multiple commercial payers. For example, Avalere's data indicates that 93 percent of Medicare claims utilize the modifier assigned to the biosimilar Zarxio while 0 percent of claims filed by commercial payers used said modifier. These statistics alone demonstrate the significant compromise of adverse event tracking outside of Medicare without individual codes for each product.

Market Evidence: Individual HCPCS Codes Could Positively Impact The Biosimilar Market

In its comments, Merck, a Biosimilars Forum member, noted that it believes that, with sufficient incentives for market entry, increasing competition can drive down market prices, especially in an environment that employs individual billing codes for each biosimilar. Merck's own recent biosimilars

market entry is an example of how a competitive biosimilars market can develop. In July, Merck launched Renflexis™ (infliximab-abda) as the second biosimilar to the reference product, Remicade. Merck launched Renflexis at a wholesale acquisition cost (WAC) price that was 35% lower than the Remicade WAC and 20% lower than the introductory WAC of the first infliximab biosimilar. A similar dynamic has been seen in the Hepatitis C market. There, the entry of multiple products into the market, including Merck's ZEPATIER™ (elbasvir and grazoprevir), resulted in dramatically lower prices – driven by a market environment that encouraged price competition, not a blending of reimbursement codes.

Provider Research: Blended Coding Impact on Providers

- A forthcoming report from the RAND Corporation acknowledges that providers could be reimbursed at a lower rate for the biosimilar than their purchase price depending on the biosimilars they stock and that this could serve as a disincentive to administer biosimilars over reference products. Sandoz confirmed the validity of this point in a provider survey performed in August, 2017. As discussed more fully below, according to this survey, volatility of the average sales price (ASP) as more biosimilars come to market is likely to deter providers from prescribing biosimilars over the reference product given the financial risk associated with a changing ASP. In addition, the blended reimbursement only factors in price, which will cause an unsustainable race to the bottom. Because the reference product maintains its own code and ASP, there is a disincentive to use a biosimilar product.

- Sandoz, a Biosimiliars Forum member, engaged an independent research firm to determine, among other things, the impact of CMS' current payment policy for biosimilars on providers. The firm surveyed 99 providers and practice managers from hematology/oncology practices and rheumatology practices who have prescribed biologics. The survey rendered several important findings relating to CMS' current payment policy, including:

    - Eighty percent of the providers surveyed preferred an alternative payment policy in which the biosimilar receives its own HCPCS code and ASP, and a majority of respondents believe this alternative policy would result in greater utilization of biosimilar products;

    - For nearly two-thirds of providers, volatility of the ASP (which occurs when new biosimilars enter the market) is likely to deter providers from prescribing biosimilars over the reference product given the financial risk involved;

    - The use of modifiers was considered at least "somewhat challenging" by 75% of practices currently prescribing biosimilars and these modifiers are not uniformly required by private payers, making the Medicare requirement of modifiers more burdensome for providers compared with of the reference product; and

    - The primary reason providers prefer the alternative payment policy in which the biosimilar receives its own code and ASP is a desire among physicians to simplify the billing and administrative aspect of prescribing biosimilars, followed by reimbursement concerns given the volatile ASP.