Biosimilars FORUM

Private Payers Are Concerned About how Coding and Payment Policy Established by CMS Could Affect Patient Access to Less-expensive Biosimilar Products

A biosimilar is a biological product licensed by the Food and Drug Administration (FDA) based on its comparability to an already FDA-approved reference product. A biosimilar is highly similar, but not identical, to its reference product, and has been proven to have the same clinical effect.[i]

In November 2015, the Centers for Medicare & Medicaid Services (CMS) finalized a controversial Medicare payment rule for biosimilars: all biosimilars related to the same reference product will share the same Healthcare Common Procedure Coding System (HCPCS) code and payment rate, separate from the reference product.[ii] This creates a single, blended Medicare reimbursement rate for the biosimilars based on the average sales price (ASP) of all biosimilars to a reference product, plus 6% of the ASP for the reference biologic.[a] According to the Medicare payment rule, reference products will still maintain their separate HCPCS codes and individual ASPs. **CMS' decision to group biosimilars into a single HCPCS code with a blended payment rate for provider use is a striking contradiction to the complexity associated with biologics, and therefore to biosimilars, too.**

In addition to grouping all biosimilars into a single HCPCS code, CMS has also required that providers add a 2-digit, randomly assigned modifier code onto each biosimilar claim to denote the manufacturer of the product. **This unprecedented coding requirement places an additional burden on providers attempting to make these newly available products accessible to their patients.**

A survey of payers representing 125 million covered lives suggests that there are concerns about how CMS policies could affect the successful adoption of these products[b]:

51% A MAJORITY OF PAYERS SURVEYED FEEL THAT

CMS was erroneous in combining all biosimilars into 1 code, separate from the reference product

44% DISAGREE WITH CMS' PAYMENT POLICY

of ASP+6% of the reference product's ASP

65% HAVE NOT REQUIRED PROVIDERS TO ENTER

the 2-digit random modifier code on their claims in order to identify the manufacturer of the biosimilar, and some feel this additional step could limit product utilization

40% OF PAYERS DO REQUIRE PROVIDERS TO DENOTE

the National Drug Code (NDC) on a claim, while others require patient-specific details or prior authorization approval. These inconsistent additional requirements could deter physician willingness to prescribe these products

[a] By law, biosimilars receive 6% of the reference product's ASP. Due to sequestration, however, the effective add-on payment amount is 4.3%.

[b] This survey was conducted by Xcenda L.L.C. in August 2017 and included 43 payers representing approximately 125 million covered lives. All respondents were familiar with biosimilars and had a role in their company's Pharmacy & Therapeutics committee. A majority (79%) represented managed care organizations; others represented integrated delivery networks, pharmacy benefit managers, specialty pharmacies, or health systems/hospitals.

Payers identified several ways in which this grouped coding policy could affect providers' willingness to adopt these products. Over one-third of respondents believed these policies would:

- **Discourage provider uptake**, and subsequent patient access, to biosimilars
- **Confuse providers and patients** about how biosimilars are only "biosimilar" to their reference product and not to one another, which could cause doubt in the safety of biosimilar products
- **Create concerns around pharmacovigilance**, as a patient may receive a biosimilar that has not been approved for the patient's condition but has been approved for other indications of the reference product
- **Inconvenience providers and increase administrative burden**, as these requirements could cause claims processing delays, erroneous billing, and subsequent claims denials for both public and private payers

CMS' policies for biosimilars could ultimately hinder access to these newly available products for Medicare patients, as well as those covered by other payers who use Medicare policy as guidance for coverage, coding, and payment determinations. Patients who could benefit from the availability of less-expensive biosimilars are likely to lose the most, as physicians could shy away from adoption, thereby limiting the potential for reductions in patient out-of-pocket expenses, overall health system savings, and the general availability of treatment options.

1. Food & Drug Administration. Information for healthcare professionals (biosimilars). https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm241719.htm. Last updated January 12, 2017. Accessed September 20, 2017.
2. Centers for Medicare & Medicaid Services. Federal Register: Revisions to payment policies under the Physician Fee Schedule and other revisions to Part B for CY 2016; Final Rule: §70885. November 16, 2015. https://www.federalregister.gov/documents/2015/11/16/2015-28005/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions. Accessed September 20, 2017.
3. Centers for Medicare & Medicaid Services. Part B Biosimilar Biological Product Payment and Required Modifiers. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html. Last updated July 26, 2017. Accessed September 20, 2017.