September 8, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1676-P

Dear Administrator Verma:

HealthyWomen is the nation’s leading independent, nonprofit health information source for women. Because we strive to educate our readers on health policy issues that will directly affect their lives, the Centers for Medicare and Medicaid Services (CMS) policy regarding reimbursement for biosimilar medications has come to our attention. We want to point out some serious problems with the current policy and urge that they be addressed expeditiously.

Currently, all biosimilar products attached to a particular reference drug are combined under a single billing code and payment rate. While this may help with administrative efficiency, it does not meet the objective of getting the right medicine to the right patient for the right condition. Here are what HealthyWomen sees as specific flaws with the current CMS biosimilars policy:

- Biosimilars, by their very nature, are not identical. Made from living organisms, biosimilar products – even those corresponding to the same reference drug – are distinctly different and may affect patients with various levels of efficacy. They should not be treated as interchangeable.

- If biosimilars are treated as identical in their CMS coding, physicians will be most likely to use the least expensive product. This approach may have no bearing on clinical efficacy and may not be the best option for the patient. Current CMS policy places economic concerns over the pursuit of better health.

- The biosimilar market is a relatively new one. A policy that will drive prescribes toward the least costly alternative will drive competitors out of the marketplace. This goes against the public interest, which will be best served by seeing current biologic drugs face greater competition from multiple biosimilar alternatives.

- Different biosimilar medications may have innumerable patient-focused variables, including differences in delivery devices, patient support programs, varying number of indications covered, physician training, home delivery options, and so on. A single code
for all biosimilars in a particular category excludes reimbursement for all of these different services and drug characteristics.

Our HealthyWomen analysis is that it would be in the best interests of patients and the physician-patient relationship to change this policy so that each biosimilar product has its own billing and reimbursement code. And, to avoid disruption in the marketplace, this change should occur as CMS is developing its final rule for the Calendar Year 2018 Medicare Physician Fee Schedule.

Thank you for your consideration and best wishes on your leadership of CMS.

Sincerely,

Beth Battaglino, RN, CEO, HealthyWomen
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