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## Amgen biosimilars report assesses current risks

April 5, 2017

### Reimbursement is just one of the issues facing biosimilar commercialization in the US

In conjunction with the Academy of Managed Care Pharmacy (AMCP) Managed Care & Specialty Pharmacy Annual Meeting (Denver, March 27-30), Amgen has released the fourth edition of its *Trends in Biosimilars Report*. The study is a useful compilation of recent research and studies on commercialization and distribution issues but, aside from statements from its editorial board members, does not present new survey data.

One of the surprising findings in the report (based on earlier research by the firm Avalere Health) is that, for Medicare patients still in the coverage gap between when full coverage under Medicare Part D kicks in, a biosimilar product can cost the patient more out-of-pocket than the originator drug. The reason: biosimilars are lumped together with generics in Medicare reimbursement policy, which have a less generous schedule for coverage.

Other commercial challenges:

- -Multiple biosimilars of the same reference product will need to be tracked electronically to tie adverse-event reporting (if any) to the appropriate drug, but some hospital recordkeeping systems are not set up to do this. As a benefit under pharmacy-benefit management systems, biosimilars' NDC codes are tracked; but when a drug is dispensed in a hospital setting, it's usually tracked as a medical benefit under the Health Care Procedure Coding System (HCPCS); no NDC and thus no specific biosimilar identification.
- In a like manner, manufacturers may choose to employ different delivery methods (vial, prefilled syringe, etc.), which will present both tracking issues and raise the importance of patient education.

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#### DIGITAL EDITION



- Two of the four biosimilars on the US market today were launched “at risk,” meaning that patent ownership issues remain to be resolved even as the products are being dispensed. Six more products have “active filings” with FDA that are expected to be acted on during this year.

The Amgen report is available [here](#).



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