

What's in the Specialty Pharmacy Pipeline?

Biosimilars, cancer drugs, and orphan drugs are heading towards FDA approval in 2017.



March 30, 2017

By [Valerie DeBenedette](#)

More specialty drugs are being approved by the FDA in each drug class, which means that competition in specialty pharmacy is increasing. The HIV drug class has 12 new drugs, psoriasis has 11, and multiple sclerosis has 10, said Aimee Tharaldson, PharmD, speaking at the Academy of Managed Care Pharmacy meeting being held in Denver.

Tharaldson is Senior Clinical Consultant of Emerging Therapeutics at [Express Scripts](#). She discussed several trends in specialty pharmacy at the meeting, noting that that 64 specialty pharmacy drugs will be losing their patents by 2021, a factor that will have a big impact on specialty spending. Drugs that are approaching approval include biosimilars, oncology drugs, and orphan drugs.

Biosimilars will present a major means of reducing specialty drug spending because dozens have patents that expire by the end of 2021. Four biosimilar agents were approved by FDA in 2016, including filgrastim-sndz, infliximab-dyyb, etanercept-szss, and adalimumab-atto, while epoetin alfa, pegfilgrastim, trastuzumab, and bevacizumab are in development.

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On the other hand, only four oncology drugs were approved by the FDA in 2016, down from 15 approved in 2015, Tharaldson said. “All this competition is not really leading to a drop in cost yet,” she noted, according to an [AMCP press release](#).

More than half of the specialty drugs in development are for orphan or rare diseases, Tharaldson noted. These drugs can cost five times as much as non-orphan drugs, she said. By 2020, about half of all pharmacy drug spending will be for orphan drugs, despite their use in less than 2% of patients.

2016 was a slower year for approvals of specialty drugs, with only 17 getting the nod from the FDA, she said. The leading specialty drug classes in 2016, based on per-member, per-year costs, were inflammatory conditions (\$118), oncology (\$61), multiple sclerosis (\$59), HIV (\$40), and hepatitis C (\$25). There are 30 specialty drugs waiting for approval in 2017, which is an approval rate that Tharaldson called “more normal.”