



iStockphoto

# Specialty Drugs and Health Care Costs

*This November 2015 fact sheet was updated in December 2016 to reflect new data.*

## Overview

Spending on prescription medications continues to rise each year in the United States.<sup>1</sup> Specialty drugs—including those used to treat conditions such as cancer and hepatitis C—represent a significant portion of this spending. The high cost of these novel therapies, which often offer advancements in patient care, raises affordability concerns for health plans, patients, and consumers.

### What is a specialty drug?

The Pew Charitable Trusts defines specialty drugs as medications with high costs for a course of treatment or a year of therapy. Some health plans also categorize drugs as specialty if they are novel therapies; require special handling, monitoring, or administration; or are used to treat rare conditions. In general, elevated costs are a distinguishing characteristic of specialty drugs. A recent survey found that 85 percent of health plans consider high cost a determining factor in identifying specialty drugs.<sup>2</sup> Medicare's definition of specialty drugs is also based on price: Pharmaceuticals costing \$600 or more per month are considered specialty.<sup>3</sup>

## Cost implications

The estimated price tag for treating a patient with a specialty drug is high: For some chronic conditions, a year of treatment with a specialty drug can exceed \$100,000.<sup>4</sup> In 2015, only 1 to 2 percent of the American public used specialty drugs, yet they accounted for approximately 38 percent of total drug expenditures.<sup>5</sup> And the price of many specialty drugs continues to rise: In 2015, specialty drug unit costs increased by 11 percent.<sup>6</sup> More patients are treating their health conditions with these drugs; utilization rose by 6.8 percent in 2015 because of increased use of existing drugs and the introduction of new pharmaceuticals.<sup>7</sup> In 1990, only 10 specialty drugs were on the market,<sup>8</sup> but there are now more than 300,<sup>9</sup> 33 of which became available in 2015 alone.<sup>10</sup> And nearly 700 specialty drugs are under development.<sup>11</sup> Because of higher prices and increased use, spending on specialty drugs represents an increasing share of total health care costs.<sup>12</sup> In 2015, specialty drug spending reached \$121 billion on a net price basis.<sup>13</sup> The estimated number of Americans with annual drug costs greater than \$50,000 increased 63 percent in 2014, from 352,000 people to 576,000.<sup>14</sup> Many of these patients take multiple drugs, and 92 percent use high-priced specialty drugs.<sup>15</sup> Importantly, patients who need specialty drugs face higher out-of-pocket (OOP) costs, because health plans often require a co-insurance payment, which is a set percentage of a drug's price. Some plans charge a co-insurance payment as high as 33 percent.<sup>16</sup>

## Managing specialty drug costs

To deal with the high cost of specialty medications, payers in public and private programs use a number of strategies to control patient OOP costs and member premiums, such as negotiating with manufacturers to obtain rebates and other discounts that help reduce the prices that plan members pay for medications. Payers also use different benefit design strategies to ensure the appropriate use of medications and manage total drug spending, including:

**Formularies and cost sharing:** Specialty drugs are typically placed in a health plan's highest drug formulary tier, where OOP costs are most expensive. Patients are often required to pay co-insurance in order to access these medications. Research shows that requiring patients to pay more out of pocket reduces their use of prescription drugs.<sup>17</sup> In their negotiations with drug manufacturers, payers can sometimes achieve lower prices by allowing patients to pay lower OOP costs for drugs.

**Step therapy:** When multiple treatment options are available for a patient's condition, plans sometimes require patients to try, and fail, treatment with a cheaper, traditional drug before letting them access a specialty drug. Patients with rheumatoid arthritis, for example, are sometimes required to attempt therapy with traditional oral medications before they can use specialty biologics.<sup>18</sup>

**Prior authorization:** These policies require a health care professional to provide documentation that validates a patient's need for a particular medication. Under most prior authorization criteria, clinical information is necessary to verify that a specialty drug is medically appropriate for a patient before coverage is granted.

## Looking forward

Many specialty drugs offer meaningful therapeutic advances over existing treatments. However, if current trends continue, the high cost of specialty drugs will have a significant impact on overall health care spending and patients' OOP costs. Pew is focused on identifying and evaluating policy options that balance the need to control overall health care spending with ensuring patient access to appropriate medications.

## Endnotes

- 1 Express Scripts, *2015 Drug Trend Report* (2016), <https://lab.express-scripts.com/lab/drug-trend-report>.
- 2 EMD Serono, *EMD Serono Specialty Digest, 10th Edition: Managed Care Strategies for Specialty Pharmaceuticals* (2014), <http://specialtydigest.emdserono.com/pdf/Digest10.pdf>.
- 3 Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (2015), <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf>.
- 4 Bradford R. Hirsch, Suresh Balu, and Kevin A. Schulman, "The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs," *Health Affairs* 33, no. 10 (2014): 1714-1720, <http://content.healthaffairs.org/content/33/10/1714.short>.
- 5 Express Scripts, *2015 Drug Trend Report*.
- 6 Ibid.
- 7 Ibid.
- 8 American Journal of Managed Care, "The Growing Cost of Specialty Pharmacy—Is it Sustainable?" (2013), <http://www.ajmc.com/payer-perspectives/0213/the-growing-cost-of-specialty-pharmacy-is-it-sustainable>.
- 9 Ibid.
- 10 Express Scripts, "FDA Approvals Set All-Time High" (2016), <https://lab.express-scripts.com/lab/insights/drug-options/fda-approvals-set-all-time-high>.
- 11 IMS Health, "Overview of the Specialty Drug Trend: Succeeding in the Rapidly Changing U.S. Specialty Market" (2014), <http://docplayer.net/4230764-Overview-of-the-specialty-drug-trend.html>.
- 12 The estimates in this section are based on published reports, some of which use different definitions for a specialty drug. However, the various authors do note that drug price or cost is used as part of their definitions of specialty.
- 13 Quintiles IMS Institute, "Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020," (2016), <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>.
- 14 On an invoice price basis, specialty spending was \$150.8 billion in 2015.
- 15 Express Scripts, "Super Spending: U.S. Trends in High-Cost Medication Use" (2015), <http://lab.express-scripts.com/lab/insights/drug-options/super-spending-us-trends-in-high-cost-medication-use>.
- 16 Kaiser Family Foundation, *Medicare Part D at Ten Years: The 2015 Marketplace and Key Trends, 2006-2015* (2015), <http://kff.org/medicare/report/medicare-part-d-at-ten-years-the-2015-marketplace-and-key-trends-2006-2015/>.
- 17 Dana P. Goldman, Geoffrey F. Joyce, and Yuhui Zheng, "Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health," *Journal of the American Medical Association* 298, no. 1 (2007): 61-69, <http://jama.jamanetwork.com/article.aspx?articleid=207805>.
- 18 Express Scripts, *Drugs That Require Prior Authorization (PA) Before Being Approved for Coverage* (2015), [https://www.express-scripts.com/art/medicare15/pdf/prior\\_authorization\\_choice.pdf](https://www.express-scripts.com/art/medicare15/pdf/prior_authorization_choice.pdf).

---

**For further information, please visit:**

[pewtrusts.org/specialtydrugs](https://pewtrusts.org/specialtydrugs)

---

**Contact:** Erin Davis, communications

**Email:** [edavis@pewtrusts.org](mailto:edavis@pewtrusts.org)

**Project website:** [pewtrusts.org/specialtydrugs](https://pewtrusts.org/specialtydrugs)

---

**The Pew Charitable Trusts** is driven by the power of knowledge to solve today's most challenging problems. Pew applies a rigorous, analytical approach to improve public policy, inform the public, and invigorate civic life.