

What is a specialty drug?¹

- Specialty pharmaceuticals are generally defined as products used to treat chronic, high-cost, or rare diseases and can be injectable, infusible, oral, or inhaled medications. Specialty pharmaceuticals tend to be more complex to maintain, administer, and monitor than traditional drugs; therefore they require closer supervision and monitoring of a patient's overall therapy.
- No third party definition
- Varies by PBM

¹NACDS White Paper November 2006
http://www.nacds.org/pdfs/membership/white_paper_specialty_pharmacy.pdf

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Why Is Specialty Rx So Special?²

Specialty drug spending reached 105.5 billion in 2016.

Typically ~1% of all prescriptions are specialty drug medications



Accounted for 66% of drug growth during 2010-2015



By 2018, specialty drug cost is expected to go up to as high as 50% of drug spend



²QuintilesIMS Report May 2017

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Top Specialty Pharmacies

Pharmacy Name	2016 Revenue	Market Share by Revenue
CVS Health	\$32 Billion	28%
Accredo	\$22.5	19%
Walgreens	\$11.2	10%
BriovaRx	\$7.8	7%
Diplomat Pharmacy	\$4.6	4%
Prime Therapeutics	\$3.0	3%
Humana Specialty	\$2.6	2%
Kroger Specialty	\$1.8	1%
Cigna	\$1.5	1%

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Key Disease Classes Driving Spend

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It isn't Hep C³

- 23,000 fewer new patients received treatment for Hepatitis C in 2016
 - 645,000 treated in the last three years
- \$1.9 Billion decrease in spend
- Still far higher than 2014 but headed down

Year	New Patients
2011	30K
2012	35K
2013	19K
2014	170K
2015	349K
2016	226K

Source: Quintiles, Whitehall, Dr.2B

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Inflammatory Conditions³

Drug Name	PMPY Cost ¹
Humira Pen	\$45.11
Enbrel	\$26.82
Humira	\$8.15
Stelara	\$8.13

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Multiple Sclerosis³

Drug Name	PMPY Cost ¹
Tecfidera	\$13.49
Copaxone	\$12.42
Gilenya	\$8.48

³2016 Express Scripts Drug Trend Report <http://lab.express-scripts.com/lab/drug-trend-report>

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Oncology⁴

Drug Name	Global Sales
Avastin	\$6.7 Billion
Rituxan	\$7.5 Billion
Herceptin	\$6.5 Billion
Imbruvica	\$5.3 Billion
Gleevec	\$4.7 Billion



⁴<https://www.thebalance.com/top-cancer-drugs-2663234>

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Specialty Driven Trend in Key Therapy Classes³

Therapy Class	2017	2018	2019
Inflammatory Conditions	29.7%	32.1%	31.7%
Oncology	22.1%	22.0%	20.5%
Multiple Sclerosis	10.3%	10.0%	10.0%
HIV	19.4%	19.4%	20.7%
Hepatitis C	-21.8%	-30.0%	-34.7%

³2016 Express Scripts Drug Trend Report <http://lab.express-scripts.com/lab/drug-trend-report>

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New Drugs in the Pipeline

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2017 Key Approvals Expected⁵

Drug	Target Indication	Population
Brodalumab	Psoriasis	7.5 million
Dupilumap	Atopic Dermatitis	17.8 million
Abaloparatide	Osteoporosis	10 million
Neratinib	Breast Cancer	2.8 million
SB-2 (infliximab) biosimilar	Multiple Indications (Remicade biosimilar)	Several million
Ibalizumab	HIV	1.1 million
CHS-1420 (adalimumab biosimilar)	Multiple Indications (Humira biosimilar)	Several million

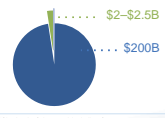
*Diplomat Pharmacy Pipeline Projections
https://fscpx.com/diplomatrx/docs/2016pipelinecapfinal_web?e=15248128/42785885

Biosimilars – Will Help A Little

The molecular makeup of each biosimilar treatment looks unique, like individual snowflakes, even though they all have similar outcomes

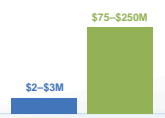


The biologic medicines market is expected to **grow to approximately 200 billion by 2015**, with biosimilars a small but growing proportion at \$2–\$2.5 billion



\$2–\$2.5B
\$200B

The cost of developing a generic small molecule is around \$2–3 million; biosimilars are estimated to cost around \$75–\$250 million to reach approval



\$2–\$3M
\$75–\$250M

Amgen: "What Are Biosimilars?" <http://www.amgenbiosimilars.com/the-basics/what-are-biosimilars/>
 Fortune: "Biosimilars may one day save your life. But what are they?" <http://fortune.com/2015/02/05/biosimilars-what-are-they/>
 Envision.

Biosimilars are coming...slowly⁶

- 2010 Congress passes Biosimilars Price Competition and Innovation Act (BPCIA)
 - Enables pathway for biologic competition
 - 12 year sales window for original molecule
- Five approved so far
 - Only two on the market
- European Costs for Biosimilars are 15-30% lower than innovator molecule

⁶<https://morningconsult.com/opinions/biosimilars-can-bend-drug-cost-curve-patients-access/>

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Specialty Rebates
Running to stand still

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FIGURE 2: SHARE OF 2015 INITIAL GROSS DRUG EXPENDITURES REALIZED BY MANUFACTURER AND NON-MANUFACTURER STAKEHOLDERS



<http://www.thinkbrg.com/media/publication/86>
3_Vanderlande_PHARMA-January-2017_WEB-FINAL.pdf

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One Result

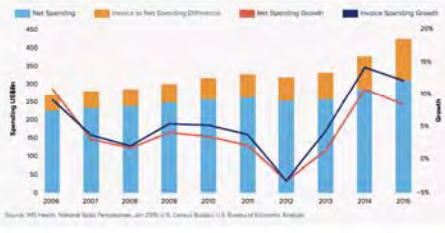
Market Access Rebates and Discounts	Negotiated Health Plan and PGM Rebates and Fees*	\$33.2	\$43.5	\$57.7
	Patient Cost Sharing Assistance	\$4.2	\$5.4	\$6.9

Stephen Ubl, president and CEO of PhRMA, highlighted a key implication of the study in [the press release](#): "The study begs an important question: Are we doing enough to ensure the growing amount of rebates and discounts flow to the patient?" said Ubl, noting that unlike care received at an in-network hospital or physician's office, a patient's cost-sharing for medicines, including payments for care received prior to meeting a deductible or from a co-insurance, is typically based on the list price of a medicine, not the net prices after rebates and discounts are factored in.

http://www.frost.com/medsubstitution/W3_Vanderweide_PhRMA_January_2017_WEB_FINAL.pdf

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Source: IMS Health, National Spacing Performance, Jan 2006 - Jan 2016; U.S. Census Bureau; U.S. Bureau of Economic Analysis

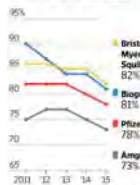
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Keeping Less

Drug companies' share of gross product sales after paying rebates and other discounts



*Excludes returns | Excludes returns and cash discounts | Source: The companies | THE WALL STREET JOURNAL

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Hard Choices to Control Costs

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Take your pick

FIGURE 24. Formulary Exclusion Classes
Based on systems that cover specialty medications under the pharmacy benefit and have exclusions in place. Multiple responses allowed.
 ▲ = Significantly higher than comparison year (p < .05)

Exclusion Class	2015 (n=117)	2016 (n=152)
Growth inhibitor	50%	45%
Parity	43%	48%
Limited C	47%	47%
Immunology infusion	32%	40%
Childhood	32%	32%
Anti-infectives	24%	22%
Cancer	14%	20%
Infusion/duration	11%	14%
Long-acting duration	14%	17%
IV	14%	17%
Oral disease	11%	14%
Other	10%	12%

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