JANUARY 2026

The Evolving Specialty Pharmacy Market: Trends in Demand, Distribution, Affordability and Policy

THROUGH LINES

trilliant health®

Executive Summary

Specialty drugs are a central component of the evolving U.S. healthcare system. While definitions vary, a specialty drug is distinguished by a combination of factors, including its molecular structure, target condition and method of administration, among other special access requirements. These drugs include biologic and traditional medications alike, and often target chronic, rare and serious medical conditions, like cancer or multiple sclerosis (MS).

Specialty drugs are also defined by their distribution – unlike a typical retail pharmacy, specialty pharmacies provide detailed medication protocols, patient education, advanced drug storage and ongoing clinical monitoring. As of 2024, there are 1,900 specialty pharmacies in the U.S.[1] Specialty drugs are increasingly driving drug spending, reshaping payer strategies and challenging traditional distribution models. Accounting for 43.3% of total drug spending in 2017, they are anticipated to account for over half of spending by 2030, while the global market size is expected to reach $965.5B.[2,3]

Despite rising demand and rapid innovation in areas such as oncology, immunology and gene therapies, stakeholders face fragmented definitions, uneven access and mounting affordability pressures. At the same time, new entrants (e.g., Walmart Health, Amazon), digital tools (e.g., telepharmacy, medication delivery services) and policy reforms (e.g., the Inflation Reduction Act (IRA), 340B Drug Pricing Program) are forcing a reassessment of how specialty drugs are delivered, reimbursed for and integrated into care.

This analysis examines five trends reshaping the specialty pharmacy market:

1. **Rising demand for specialty drugs is driven by the growing prevalence of chronic and complex conditions.**
2. **Escalating costs amplify affordability and sustainability pressures for payers, employers and patients.**
3. **Biologics, gene therapies, CAR-T treatments and biosimilars are transforming the drug pipeline as they increasingly dominate development and launch strategies.**
4. **The distribution landscape is shifting as major stakeholders and new entrants compete for market share and reimagine patient access models.**
5. **Policy and regulatory reforms are influencing specialty drug pricing, reimbursement and distribution models.**

These trends illustrate a market at a tipping point, where rising demand for complex therapies, accelerating innovation and escalating costs are testing traditional pricing models (Figure 1). Stakeholders face difficult tradeoffs between broad patient access, affordable premiums and sustainable manufacturer investment – particularly in rare and high-cost conditions. To remain viable, the sector must redefine how specialty drugs are financed, distributed and supported to balance innovation with affordability and equity in care delivery.

The specialty pharmacy market operates at the intersection of innovation, cost and access. As therapies become more personalized and costly, vertically integrated companies continue to control a substantial share of the market and new entrants are seeking to innovate the distribution process, while payers and policymakers test new models to manage affordability and assess value.

FIGURE 1. Specialty Drug Market Overview

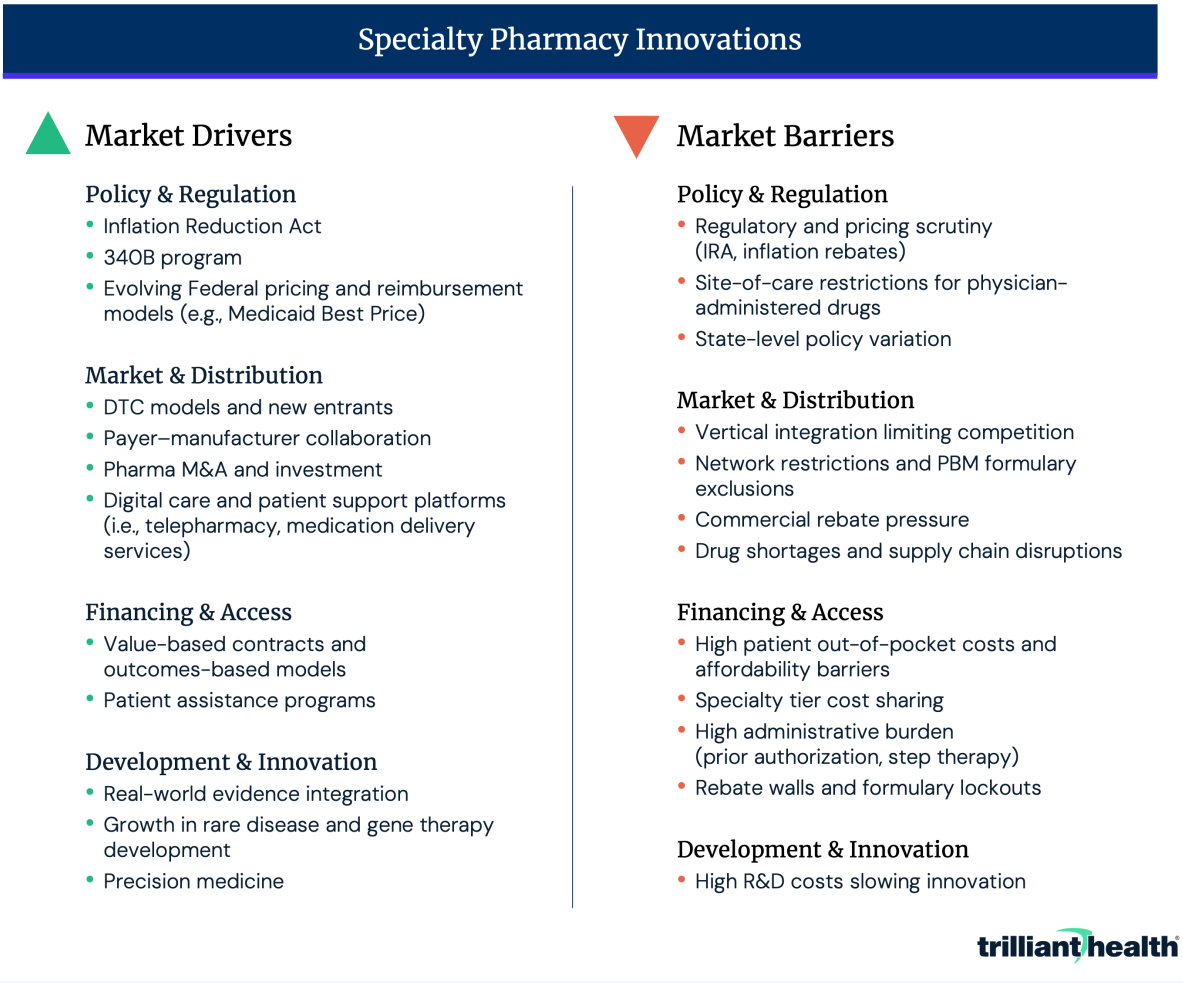
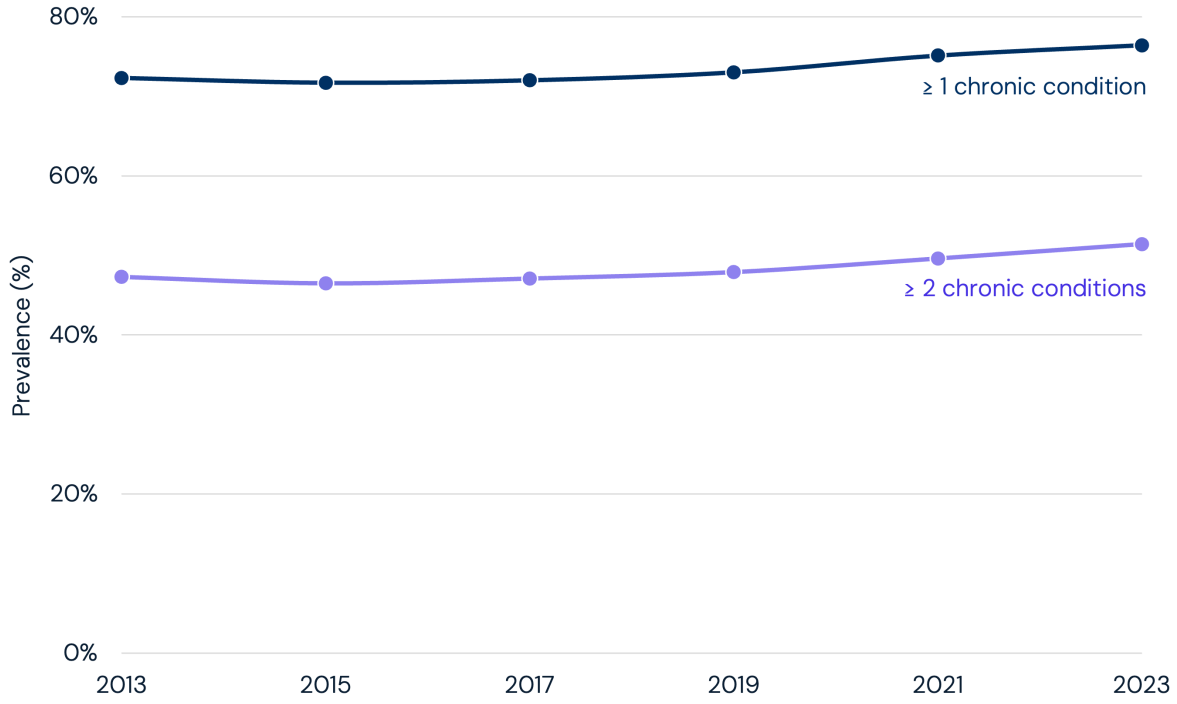


Table of Contents

Rising Demand for Specialty Drugs Is Driven by the Growing Prevalence of Chronic and Complex Conditions

Demand for specialty drugs continues to grow as the health status of Americans worsens and chronic disease prevalence grows (Figure 2). Close to 80% of U.S. adults live with at least one chronic condition, and more than half have multiple chronic conditions such as diabetes, heart disease, cancer and obesity.[4] The combination of these chronic conditions drive close to 90% of the nation's $4.9T in annual healthcare spending, underscoring the outsized burden they place on patients and the healthcare system.[5] While the prevalence of chronic disease among adults has increased only modestly over the past decade – from 72.3% 2013 to 76.4% in 2023 – the magnitude is large and increasing, driving sustained demand for advanced treatments.[6]

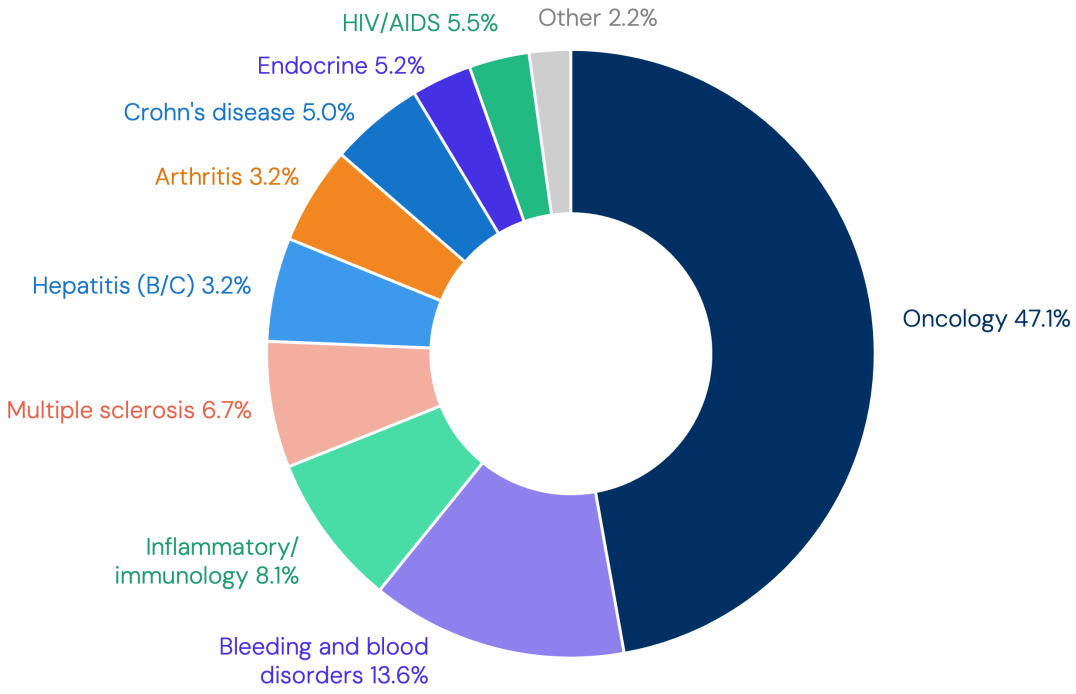
FIGURE 2. Chronic Condition Prevalence in U.S. Adults, 2013-2023



Note: Share of drugs = weighted average of category shares across three specialty pharmacies (CVS, Express Scripts, Accredo Evernorth), weighted by each pharmacy's drug list size (pooled counts).
Source: CVS and Cigna.

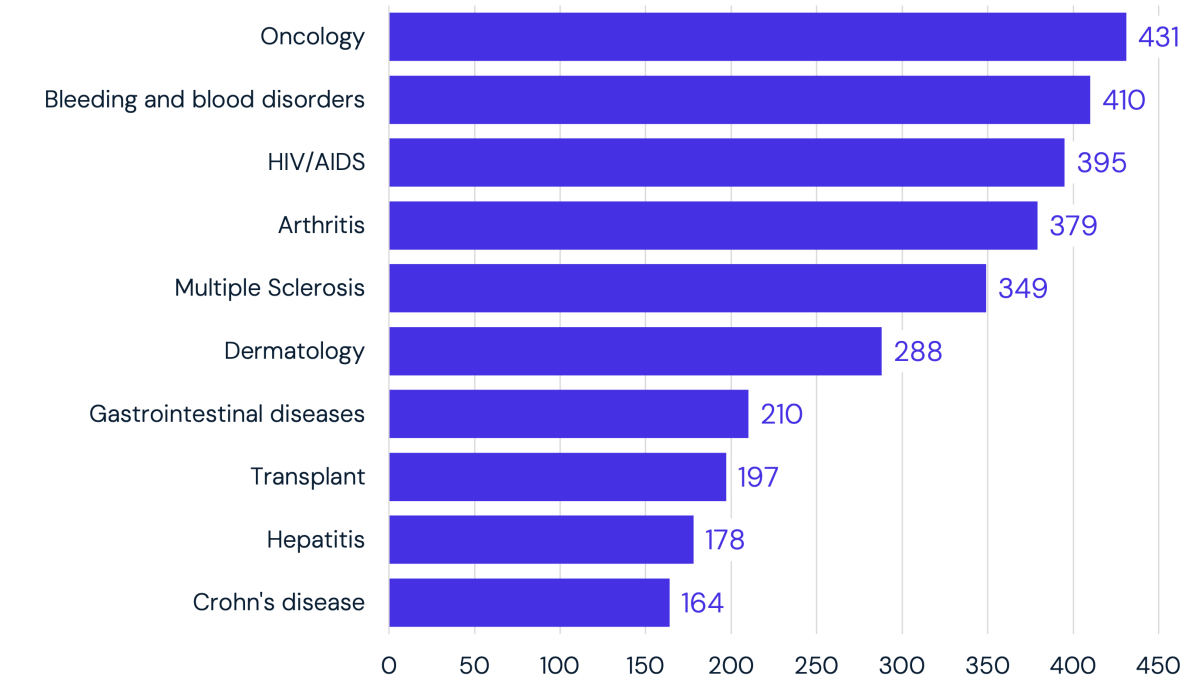
Within chronic disease management, demand for specialty drugs is heavily concentrated in autoimmune and inflammatory conditions such as rheumatoid arthritis, MS, psoriasis, Chrohn's disease, certain cancers and HIV/AIDS.[7] Oncology drugs make up the greatest share of specialty drugs (47.1%), followed by bleeding and blood disorders (13.6%) and inflammatory conditions (8.1%) (Figure 3). Specialty pharmacies often focus on specific therapeutic areas, sometimes multiple. In 2020, 431 specialty pharmacies focused on dispensing oncology drugs, followed by 410 pharmacies dispensing blood disorder therapies (Figure 4). There is also an element of supply-induced demand in the growing specialty pharmacy market. While many chronic conditions have existing, effective treatment options, some are now being replaced by higher-cost biologics or disease-modifying drugs, which increases overall per-patient spending.[8]

FIGURE 3. Most Common Therapeutic Areas, by Share of Specialty Drugs, 2025



Note: Share of drugs = weighted average of category shares across three specialty pharmacies (CVS, Express Scripts, Accredo Evernorth), weighted by each pharmacy's drug list size (pooled counts).
Source: CVS and Cigna.

FIGURE 4. Most Common Therapeutic Areas, by Number of Specialty Pharmacies, 2020



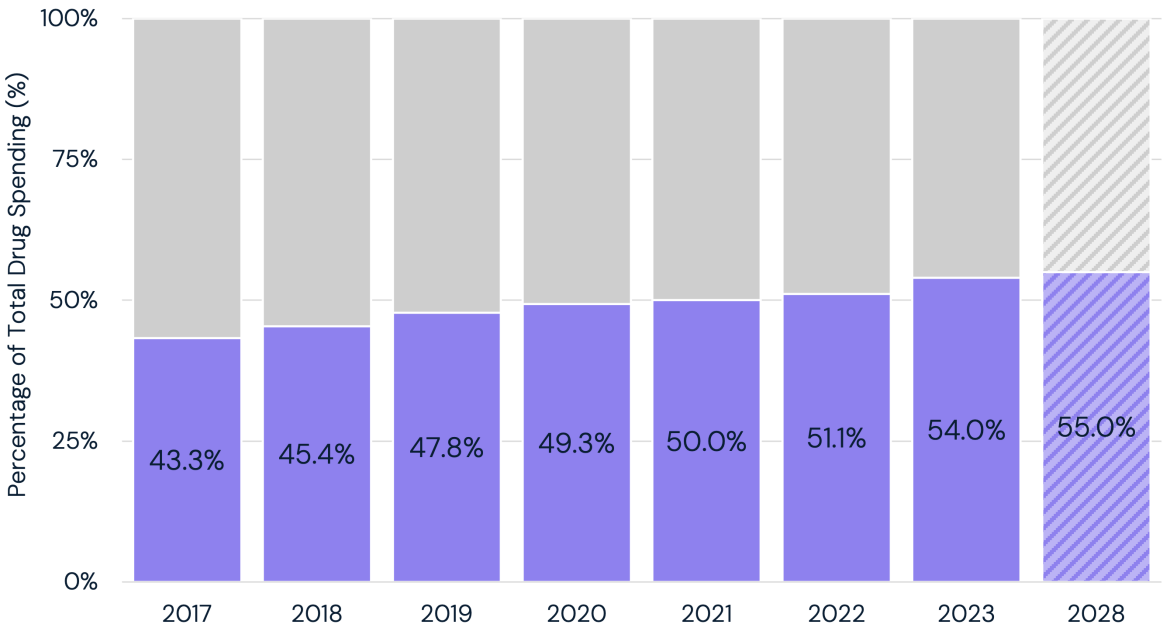
Note: Total number of specialty pharmacies n=988.
Source: Definitive Healthcare.

Specialty drug pipelines are increasingly shaped by rare and orphan diseases, which account for nearly half of 2025 FDA drug approvals.[9] More than 7,000 rare diseases affect over 30M people in the U.S., yet only 500 rare diseases have FDA-approved treatments, since there is little financial incentive to invest in therapies that affect such a small population.[10,11] The most common high-cost rare disease therapies treat conditions such as cystic fibrosis, MS, hemophilia and certain hereditary cancers.[12,13] Unlike chronic conditions, rare disease therapies often address previously untreated conditions, typically serving small patient populations with very high per-patient costs.[14] These high costs help explain why therapies for rare diseases, such as MS, account for a growing share of specialty drug spending despite treating relatively few patients.

Escalating Costs Amplify Affordability and Sustainability Pressures for Payers, Employers and Patients

Specialty drug spending continues to grow rapidly, intensifying affordability concerns for payers, employers and patients. Importantly, growing specialty pharmacy costs impact everyone, not just those taking specialty medications, in the form of higher premiums. In the U.S., drug spending totaled $437B in 2023 – after accounting for rebates and discounts – with specialty drugs representing 54% of that total (Figure 5).[15] The size of the specialty drug market increased from $92.5B in 2023 to $129.2B in 2024, and projected to reach nearly $965.5B by 2030 – a compound annual growth rate of 39.8%.[16] Globally, specialty medicines are expected to account for 43% of total drug spending by 2028 and more than 55.0% in leading developed markets, such as the U.S.[17]

FIGURE 5. Percent of Drug Spending Attributed To Specialty Drugs, 2017-2023 and 2028

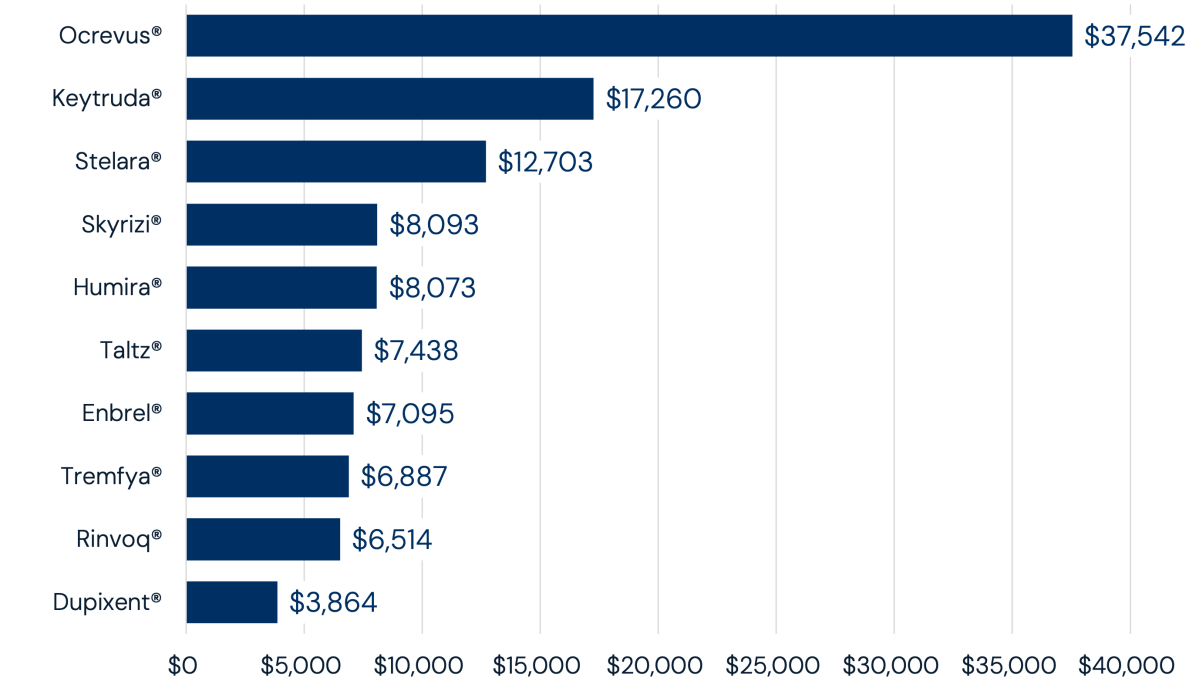


Note: 2028 is the projected share of total drug spending in the U.S.
Source: Assistant Secretary for Planning and Evaluation, 2022, CarelonRx and IQVIA.

trilliant health

Cost trajectories also diverge based on how specialty drugs are administered and reimbursed. Specialty drugs billed under the pharmacy benefit have seen cost relief from biosimilar competition, as in the case of Humira®, while therapies covered under the medical benefit – such as infused biologics and gene therapies – remain expensive and continue to increase total spending.[18] The top drugs by spend primarily treat autoimmune and inflammatory conditions: Humira®, Stelara® and Skyrizi® (Figures 6, 7).[19]

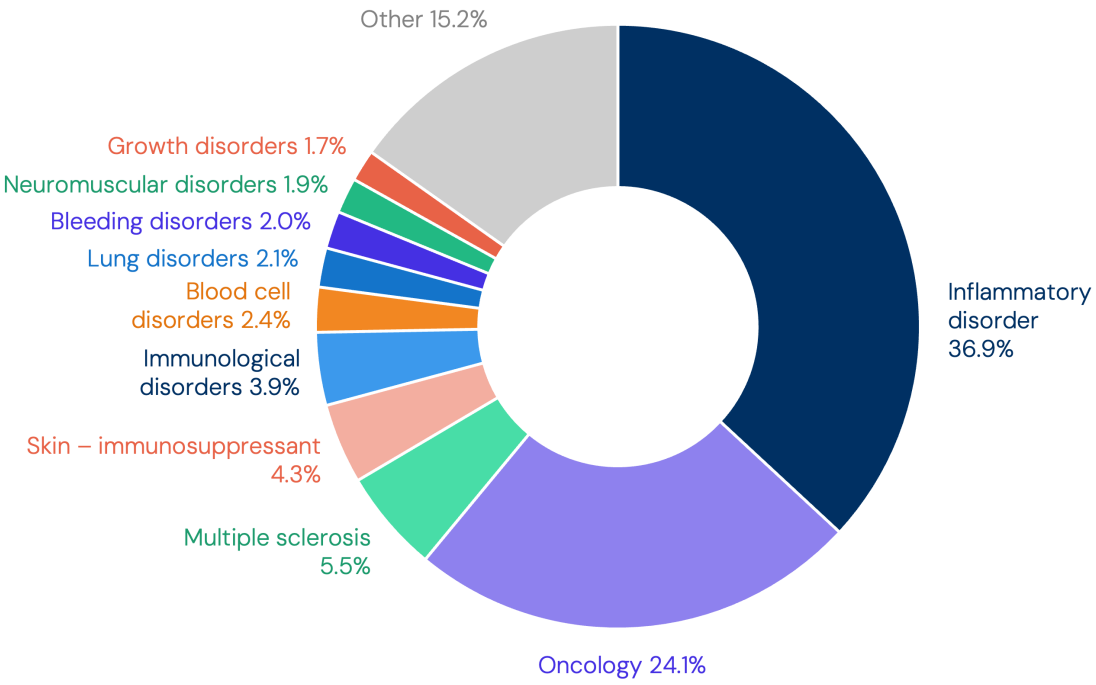
FIGURE 6. Top 10 U.S. Specialty Drugs, by Spend, 2024



Note: Prescription cost normalized to 30 day equivalents.
Source: Pharmaceutical Strategies Group.

trillianthealth

FIGURE 7. Top 10 Categories for Specialty Drug Spend, 2024



Source: Pharmaceutical Strategies Group

trillianthealth

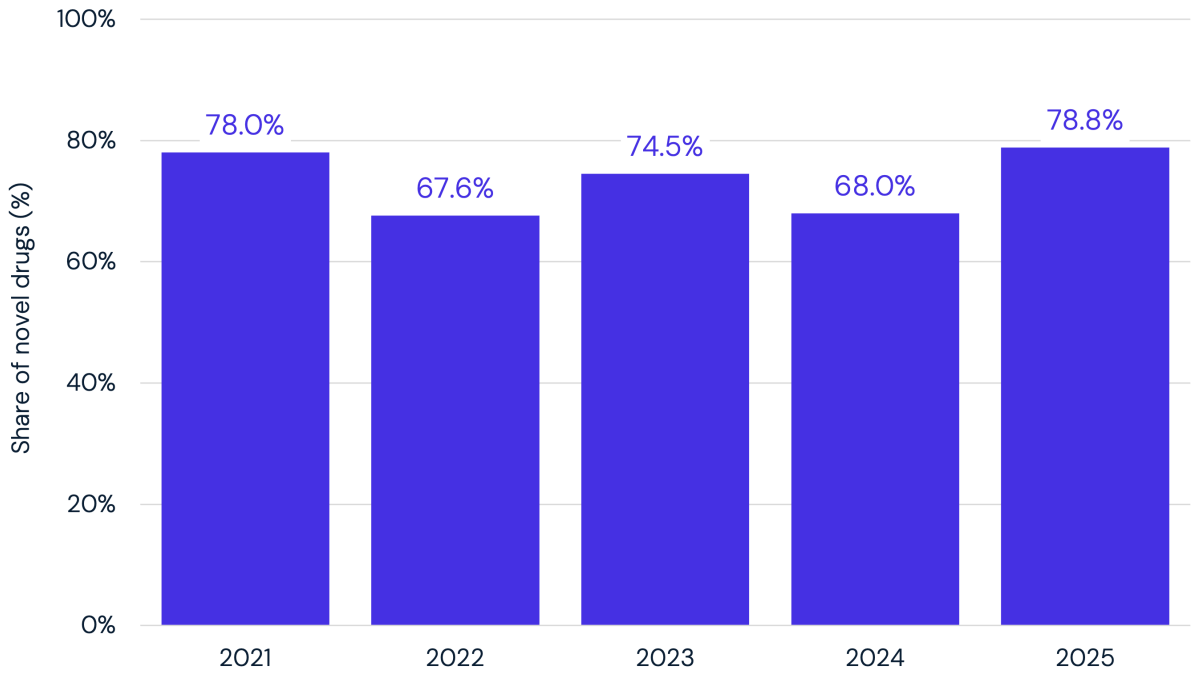
Financial implications extend beyond payers and pharmacy benefit managers (PBMs) to employers and patients. According to the International Foundation of Employee Benefit Plans survey results, specialty drugs and cell and gene therapies (CGTs) are among the top drivers of rising health benefit costs, contributing to a 7% increase in overall cost trends.[20] Employers are responding with utilization management tools – including prior authorization, quantity limits, case management and disease management programs – alongside growing reliance on outcomes-based contracts that tie payment to patient outcomes and real-world effectiveness.[21] America's Health Insurance Plans (AHIP) reports that providers charge an average of 42% more than specialty pharmacies for the same medication, underscoring the role of distribution channels in affordability.[22]

Specialty drugs account for a disproportionate amount of overall employer spending. In Delaware, 44% of total drug spending in fully insured commercial plans came from just 1% of pharmacy claims.[23] This concentration illustrates the sustainability challenge: a small set of therapies exerts an outsized impact on payers and patients, reinforcing the urgency for new payment models, strategic benefit design and targeted cost-control mechanisms. Given that a small fraction of therapies drives a large share of spending, patients prescribed these specialty drugs can face disproportionately high out-of-pocket (OOP) costs, highlighting the need for benefit designs that mitigate financial barriers to access.[24]

Biologics, Gene Therapies, CAR-T Treatments and Biosimilars Are Transforming the Drug Pipeline As They Increasingly Dominate Development and Launch Strategies

The specialty drug pipeline has expanded rapidly, reshaping how complex conditions are managed or cured. In the mid-1990s, fewer than 30 specialty drugs were available, but accounted for nearly 80% of the 55 novel drugs approved by the FDA in 2025.[25,26] Over the past few years, the share of FDA novel drugs designated as specialty drugs has fluctuated between 67.6% and 78.8% (Figure 8).

FIGURE 8. Share of FDA Novel Drug Approvals Meeting Specialty Drug Criteria, 2023-2025

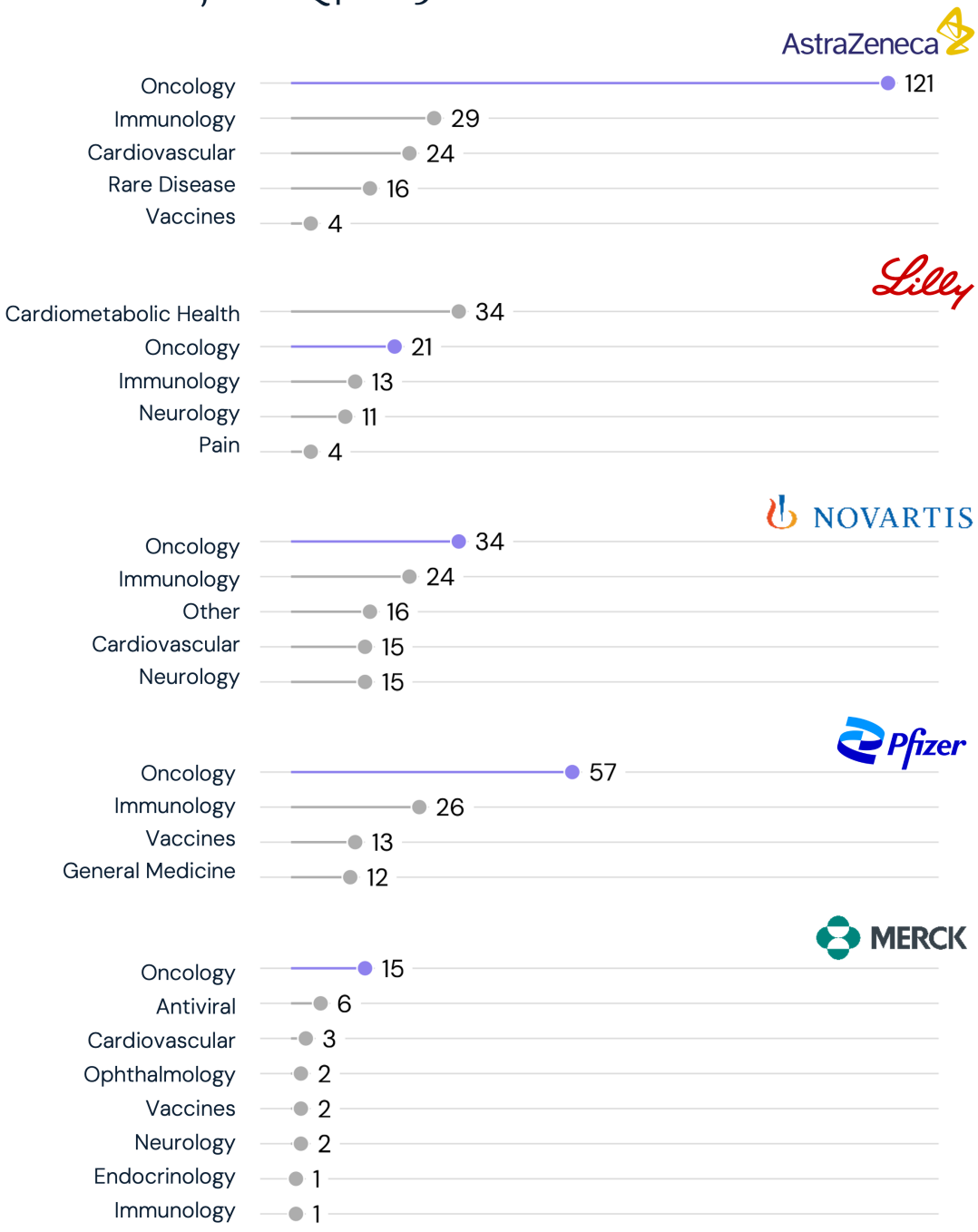


Note: Specialty share is calculated using a conservative operational definition (biologics; oncology/hematology; rare/complex conditions with limited distribution or high-touch requirements). 2025 data is year to date, last updated October 2025.
Source: Food and Drug Administration.

trilliant health

Today, specialty therapies represent about 75% of the 7,000 drugs under development.[27] Oncology and immunology dominate the pipeline (Figure 9), with 100 oncology therapies anticipated to launch over the next five years, increasing spending from $224B to more than $440B by 2028.[28]

FIGURE 9. Clinical Development Pipelines of Major Biopharmaceutical Manufacturers, as of Q4 2025



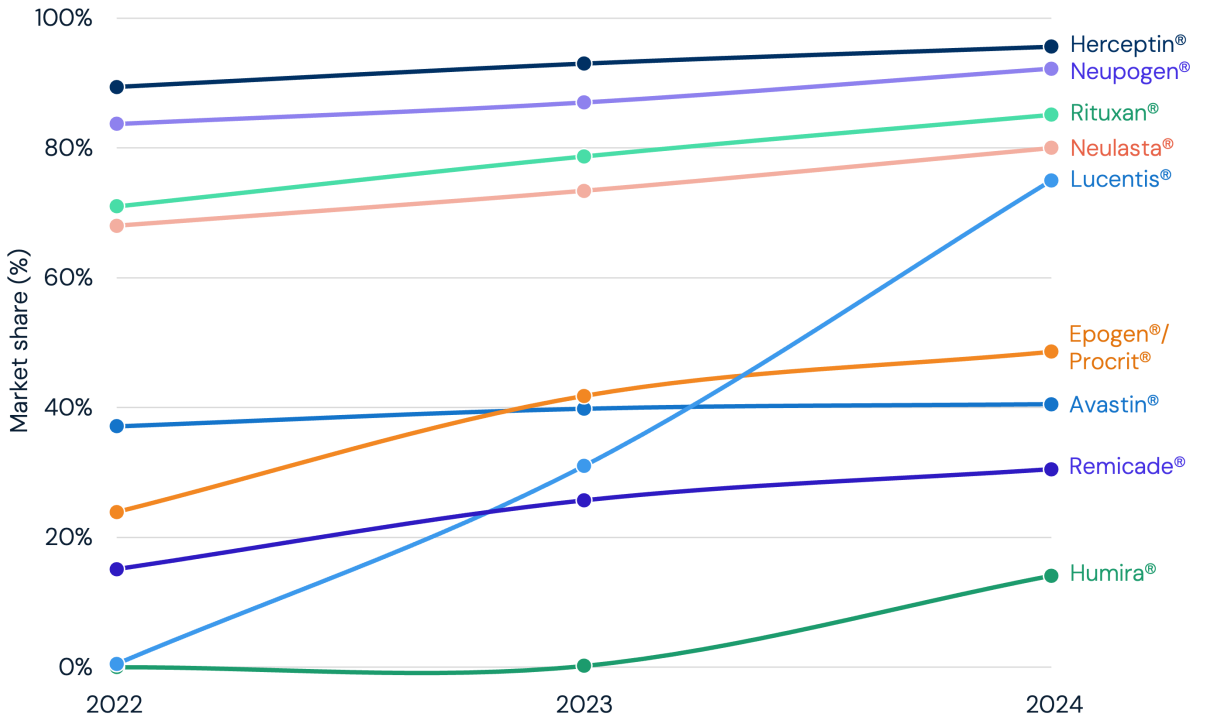
Source: Company clinical development pipelines.

trilliant health

Biosimilars have the potential to disrupt the specialty pharmacy market, with growing uptake in oncology and autoimmune disease classes despite coverage and prescribing barriers. Designed to replicate the therapeutic effects of originator biologics, biosimilars typically launch at approximately 50% of the reference product price and have reduced average sales prices of corresponding biologics by 25%, on average.[29] Between 2021 and 2025, biosimilar savings could reach $38.5B – about 5.9% of projected biologic spending.[30] As of 2025, FDA had approved 76 biosimilars across 19 unique molecules, with 55 already launched in the U.S.[31] Uptake is particularly strong in oncology and autoimmune classes, with biosimilars for Humira®, Stelara®, Enbrel®, Lucentis®, Remicade® and others gaining traction.[32,33] Generic or biosimilar equivalents are expected to be available for nearly half of the top 25 specialty drugs, potentially exposing $100B in annual drug spend to competition.[34]

Despite potential cost savings, the adoption of biosimilars among other therapeutic areas has been slower than anticipated (Figure 10). Several systemic barriers to biosimilar adoption exist related to coverage and prescribing. For example, "rebate walls" and exclusionary contracting can keep originators in preferred positions even when biosimilars are less expensive than originator biologics.[35] Hospitals participating in 340B tend to have a lower biosimilar uptake compared to hospitals that do not participate in the program, which is consistent with revenue incentives that can favor higher-priced brand products in outpatient settings.[36] PBMs can either exclude biosimilars from their formularies, place them on higher tiers with higher OOP costs, or place them at the same level of a brand-name drug, without providing member initiatives to encourage biosimilar uptake.[37] In addition, state-specific laws and regulations can influence physician prescribing decisions, as states with stricter substitution laws have a lower likelihood of filling interchangeable biosimilars following market launch.[38] Barriers to uptake for healthcare providers include limited knowledge of biosimilars, along with safety and efficacy concerns.[39] Healthcare providers may also face administrative barriers such as prior authorizations or step therapy requirements. Patients might also hesitate to switch from biologics to biosimilars out of efficacy concerns.[40] Also, the potential cost savings often do not reach patients. Biosimilar competition has not consistently been shown to lower patient OOP costs in commercial plans, which might disincentivize clinicians and patients from switching.[41]

FIGURE 10. Biosimilar Market Share of Originator Product, 2022-2024

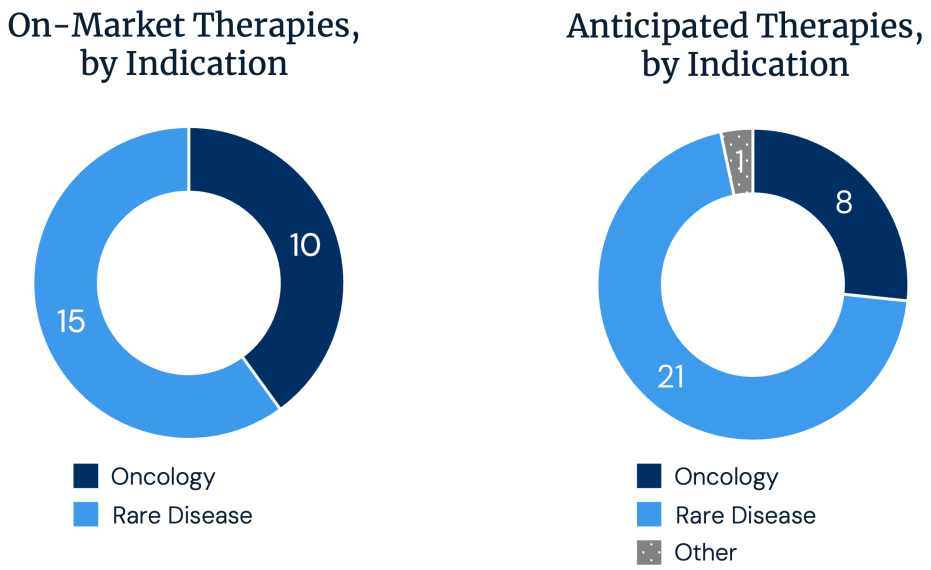


Note: Humira's first biosimilar launched in 2023.
Source: Pharmaceutical Strategies Group.

trilliant health

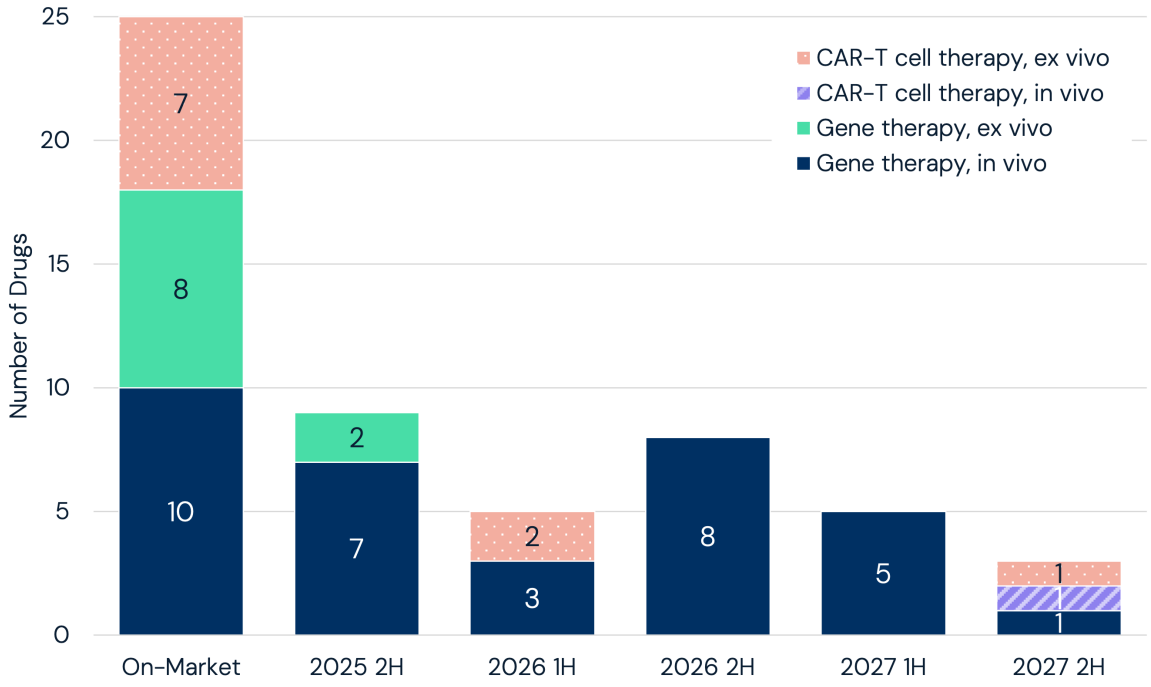
Alongside biosimilars, CGT innovation is accelerating. As of October 2025, 46 CGTs had received FDA approval, with more than 500 additional therapies in the pipeline.[42,43] The FDA anticipates 10-20 new CGT approvals annually, spanning conditions from cancer and cystic fibrosis to hemophilia, Alzheimer's, Parkinson's and schizophrenia (Figures 11, 12).[44] Notably, the FDA granted accelerated approval in 2024 to lisocabtagene maraleucel (Breyanzi®), a CAR-T therapy for chronic lymphocytic leukemia and small lymphocytic lymphoma.[45] These advanced therapies, while high cost, represent a growing share of the specialty pipeline and highlight new operational pressures for specialty pharmacies – from navigating limited-distribution networks and payer authorization to managing supply-chain logistics, genetic testing coordination and long-term patient monitoring.[46,47]

FIGURE 11. On-Market and Anticipated Cell and Gene Therapies, by Specialty, 2025



Source: CVS, Gene Therapy Report, Q1 2025–Q4 2027; U.S. Food and Drug Administration "Approved Cellular and Gene Therapy Products."

FIGURE 12. Gene and CAR-T Cell Therapies Already on Market or With Projected Launch Years Between 2025 and 2027

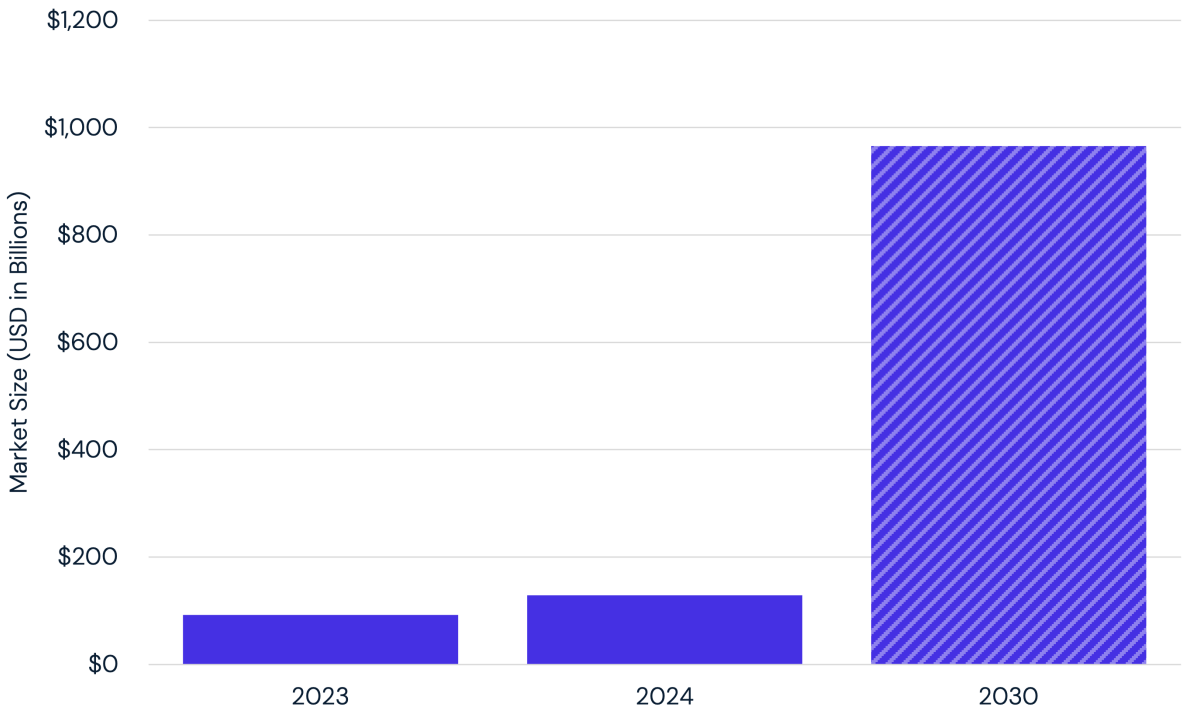


Note: CGT denotes cell and gene therapy; CAR-T denotes chimeric antigen receptor. Rare disease drugs are for diseases with less than 200,000 potential U.S. patients.
Source: CVS, Gene Therapy Report, Q1 2025–Q4 2027; U.S. Food and Drug Administration "Approved Cellular and Gene Therapy Products."

The Distribution Landscape Is Shifting As Major Stakeholders and New Entrants Compete for Market Share and Reimagine Patient Access Models

The specialty drug market is projected to grow steadily through 2030, underscoring the continued importance of distribution in shaping market dynamics (Figure 13). Dispensing is highly concentrated – in 2024, the three largest specialty pharmacies accounted for two-thirds of all prescription revenues, each owned by vertically integrated organizations that also operate PBMs (Figure 14). Despite this consolidation, hospitals and health systems are expanding their specialty pharmacy presence, representing 27% of accredited specialty pharmacies in 2023, up from 15% in 2017.[48] Independent pharmacies make up a larger share of accredited locations but continue to lose revenue share, underscoring how scale and integration shape competitive advantage.

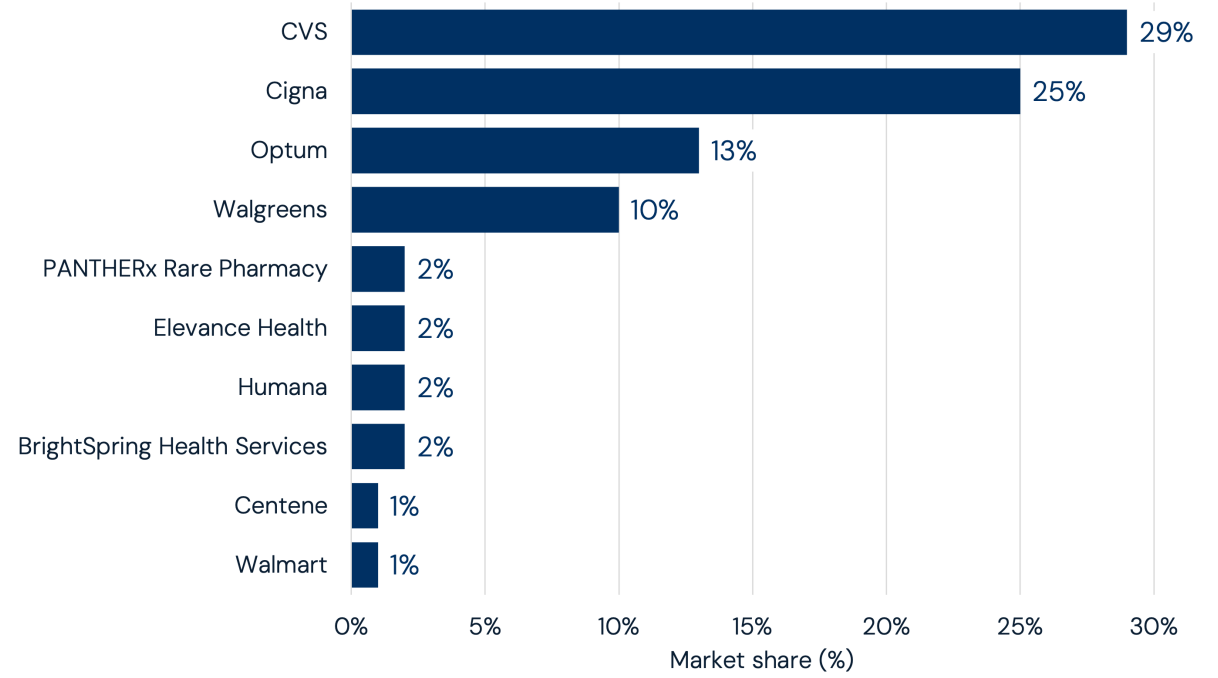
FIGURE 13. Specialty Pharmaceuticals Market Size, 2023-2030



Note: 2030 is projected market growth.
Source: CarelonRx.

trilliant health

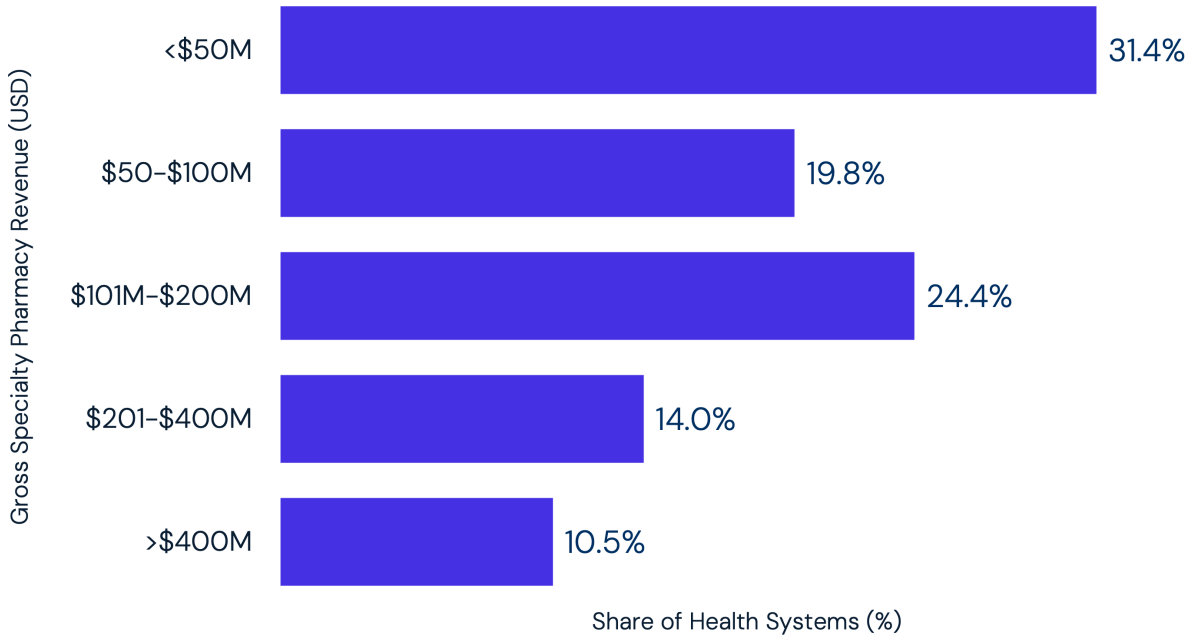
FIGURE 14. Top 10 U.S. Specialty Pharmacy Organizations, by Market Share, 2024



Source: Drug Channels

Specialty pharmacies represent a growing but fragmented market. Most operations remain relatively small – about 75% of health systems reported gross specialty pharmacy revenue of $200M or less in 2022 – reflecting barriers to entry such as limited access to payer networks, declining reimbursements and challenges recruiting qualified clinical staff (Figure 15). Still, hospitals and health systems view specialty pharmacy as strategically important, particularly given its link to 340B participation, integrated care coordination and improved patient retention.

FIGURE 15. Share of Health Systems by Gross Specialty Pharmacy Revenue, 2022



Source: Drug Channels

New entrants, such as CVS, Walgreens, Amazon and Walmart are expanding into the specialty pharmacy market after pivoting from primary care delivery. CVS is rapidly expanding specialty pharmacies via Caremark and Cordavis, while Amazon Pharmacy is expanding its offerings to include specialty medications (Figure 16). These organizations are shifting away from low-acuity clinic models that proved financially unsustainable and instead leveraging their core pharmacy operations, patient management capabilities and supply chain efficiencies to compete in specialty pharmacy.[49] The decision reflects a more strategic approach – prioritizing proven revenue generators aligned with existing expertise over ventures into less profitable areas.

FIGURE 16. Specialty Pharmacy Retailers

Retailer	Primary Care Entry	Initial Primary Care Strategy	Evolved Primary Care Strategy	Primary Care Status	Specialty Pharmacy Strategy
CVS Health	**2014** (MinuteClinic expansion) **2021** (Acquisition of Oak Street Health)	Acquired Oak Street Health for $10.6B to operate value-based senior primary care clinics combined with existing MinuteClinic and Aetna Medicare Advantage.	Slowed expansion of Oak Street clinics; some closures reported; facing profitability and integration challenges.	**Active, but scaling back**	Aggressively expanding specialty pharmacy via Caremark and Cordavis.
Walgreens	**2021** (Major investment in VillageMD)	Invested $6B for majority stake in VillageMD to co-locate full-service primary care clinics in stores.	Announced in early 2024 that it would close ~160 VillageMD clinics and sell majority stake amid $5B writedown.	**Exit**	Focused on specialty growth via Shields Health Solutions (acquired 2022).
amazon	**2019** (Amazon Care) **2022** (Acquisition of One Medical)	Launched Amazon Care; later acquired One Medical for $3.9B to scale hybrid primary care.	Shut down Amazon Care in 2022. One Medical still operating but experiencing slow growth and unclear integration with Amazon Prime.	**Pivoted**	Entered specialty pharmacy in 2023 via Amazon Pharmacy, now expanding offerings to include specialty medications.
Walmart	**2019** (Walmart Health centers)	Built de novo primary care clinics offering low-cost care near stores, targeting self-pay and Medicare Advantage patients.	In 2024, announced exit from 51 health centers and halted further expansion, citing unsustainable costs. Maintains a few clinics in select markets.	**Exit**	Exploring partnerships and payer collaborations in specialty. No standalone specialty pharmacy brand, but strong retail pharmacy infrastructure could support future entry.

Source: Publicly available company information.

trilliant health

Manufacturers are also reshaping specialty distribution through direct-to-consumer (DTC) platforms. Drugmakers such as Eli Lilly, Pfizer, Bristol Myers Squibb and Novo Nordisk have begun selling select brand-name therapies directly to patients, bypassing traditional PBM and pharmacy intermediaries.[50] While currently limited in scale, these platforms signal a potential shift in control over pricing, data and patient engagement – particularly for high-demand, chronic-use therapies like GLP-1s, such as Zepound®, available through Ely Lilly's DTC platform, LillyDirect®. If adopted more broadly, manufacturer DTC channels could disrupt existing payer and specialty pharmacy relationships, altering how specialty drugs are accessed and paid for.

Patient access models are a key differentiator in this competitive landscape. Specialty medications often require cold-chain handling, strict chain-of-custody protocols and complex prior authorization processes. Specialty drugs also present unique challenges in rural and low-income areas. Many therapies require infusion, injection or administration by a healthcare provider, which can be difficult to access in rural areas. This creates both an urgent need and a significant market opportunity for specialty pharmacies to serve vulnerable populations and fill gaps in care delivery by providing medications, financial navigation and high-touch support to patients managing serious disease.[51]

Specialty pharmacies are embedding services to navigate these barriers, such as centralized message centers, e-prescribing systems that integrate across electronic health records, and trained clinicians who guide providers through appeals when prior authorization is denied.[52] Many also deploy patient advocates who help individuals manage high costs and insurance complexities.

Technology is further reshaping distribution and patient access. Telepharmacy, AI-driven adherence reminders and medication delivery services simplify access and extend reach beyond traditional brick-and-mortar settings.[53] By combining specialized services with digital solutions, specialty pharmacies are evolving beyond dispensaries into full-service access facilitators, positioning themselves as essential partners in managing the growth of specialty drugs.

Policy and Regulatory Reforms That Influence Specialty Drug Pricing, Reimbursement and Distribution Models

Specialty drug pricing and distribution are shaped by an increasingly complex policy environment focused on patient access, affordability and the financial sustainability of the specialty drug market. Federal reforms such as the IRA have already begun to reset expectations for OOP spending in Medicare Part D, most notably with the $2,000 annual cap that took effect January 1, 2025.[54,55] Once a beneficiary's 2025 OOP spending on Part D reaches $2,000, their patient responsibility is $0 for the remainder of the year. The Congressional Budget Office (CBO) projects the IRA's drug pricing provisions will reduce the Federal deficit by $237B between 2022 and 2031 (CBO). More recently, CMS announced that certain Medicare beneficiaries will see reduced coinsurance on 64 Part B drugs, reflecting ongoing efforts to mitigate cost burdens for infused and physician-administered therapies.[56]

The Trump Administration has introduced additional policy directives aimed at lowering drug costs and reshaping pricing dynamics. Two 2025 executive orders (EOs) – "Lowering Drug Prices by Once Again Putting Americans First" (signed April 15) and "Delivering Most-Favored-Nation (MFN) Pricing to American Patients" (signed May 12) – direct the U.S. Department of Health and Human Services (HHS) to study and implement policies that would reduce drug prices.[57,58] These include adjustments to the Medicare Drug Price Negotiation Program, testing new Centers for Medicare and Medicare Innovation (CMMI) models for high-cost drugs, expanding generic and biosimilar adoption and enhancing PBM financial transparency under the Employee Retirement Income Security Act (ERISA).[59] The MFN EO further sets a goal of aligning U.S. drug prices with those paid in other OECD nations, initially through voluntary manufacturer agreements and DTC channels, with potential rulemaking to follow.[60] Implementation has begun through high-profile deals with major manufacturers. Pfizer, AstraZeneca and Merck's EMD Serono have each reached voluntary MFN agreements that provide state Medicaid programs and consumers with access to discounted prices while committing to expanded U.S. manufacturing and R&D.[61,62,63] All three companies will participate in the TrumpRx.gov direct purchasing platform, which will allow patients to buy select medicines at reduced cash prices once the site launches in 2026. Pfizer's agreement includes discounts for Medicaid patients on several products including Eucrisa® for atopic dermatitis (80% discount), Xeljanz® for rheumatoid arthritis, psoriatic arthritis and ulcerative colitis (40% discount) and Zavzpret™ for migraines (50% discount).[64] AstraZeneca will extend MFN prices to eligible patients with prescriptions for chronic diseases, offering discounts of up to 80% off list prices.[65] EMD Serono's agreement offers up to an 84% discount on its full in-vitro fertilization (IVF) drug portfolio including Gonal-F®, Cetrotide® and Ovidrel®, saving eligible patients up to $2,200 per IVF cycle.[66] If this voluntary approach proves successful, it could accelerate DTC distribution models and exert new downward pressure on prices – particularly for high-cost specialty and biologic therapies.

Another area of policy significance is the 340B Drug Pricing Program, which has grown substantially and become a key lever in the specialty pharmacy market. According to the CBO, covered entities' purchases through 340B have expanded in recent years, raising questions about whether discounts are translating into lower patient OOP costs or primarily benefiting hospital systems and contract pharmacies. The rapid growth of 340B has also fueled debate about its impact on drug pricing overall and on the distribution of specialty drugs in particular. Policymakers are weighing options to improve transparency and oversight, with implications for how manufacturers, pharmacies and providers engage with the program.[67]

At the same time, oversight and definitions of what constitutes a "specialty drug" remain fragmented. A 2020 Office of Inspector General (OIG) survey found that Medicaid programs used more than 100 different characteristics to categorize specialty drugs, highlighting wide variation in how states and managed care organizations apply cost management strategies.[68] Part D applies a clearer cost-based definition – drugs costing $670 or more per month – but a lack of standardization across programs complicates both regulatory enforcement and payer strategies.[69] As high-cost therapies continue to enter the pipeline, payers will face increasing pressure to anticipate coverage and reimbursement impacts.[70]

Taken together, these shifts illustrate the push and pull between innovation, affordability and regulatory oversight. Policies that cap patient costs or reshape reimbursement will alter incentives across the supply chain, while unresolved issues – from fragmented specialty drug definitions to the growing role of 340B – add layers of uncertainty. Stakeholders will need to adapt business models and contracting strategies to stay ahead of evolving Federal and state policy, balancing near-term compliance with long-term financial and access sustainability across the specialty drug market.[71]

Conclusion

The specialty drug pipeline is robust and will continue to be dominated by highly innovative therapies, such as CGTs and precision biologics. While these advances promise transformative outcomes, they also bring unprecedented launch prices and uncertain long-term value. FDA continues to emphasize expedited review and accelerated approval pathways for these therapies, reflecting a commitment to innovation, while still emphasizing the importance of post-market evidence and safety validation.[72] Payers will need to refine evidence requirements, risk-sharing models and outcomes-based contracts to manage budget impacts. Providers and health systems will increasingly face operational challenges in delivering complex therapies, while patients may confront widening disparities in access if affordability and coverage policies do not keep pace.

The competitive landscape for specialty pharmacy will continue to shift as nontraditional entrants like retailers and technology-driven platforms test new access models. Integrated payer–PBM–provider structures will likely tighten control of specialty dispensing, but employer groups and consumers may push back if transparency and affordability gains are limited. Pharmacies and manufacturers will need to adapt to new distribution channels, specialty carve-outs and site-of-care strategies. The pace of biosimilar adoption and the effectiveness of benefit designs in redirecting utilization will determine the balance of power across the specialty drug supply chain.

The persistence of cost-sharing differences between medical and pharmacy benefits will determine the extent of affordability challenges across patient populations. In addition, projections show notable premium increases in 2026, with a median proposed increase of 18% nationally.[73] Payers will face pressure to manage premium growth, while preserving access to high-cost specialty therapies, likely through a combination of benefit redesign, utilization management and outcomes-based contracting to contain spending. Employers and payers are expected to expand copay smoothing programs, accumulator adjustments and benefit redesigns to reduce financial toxicity. Patient advocacy groups and policymakers may intensify pressure to ensure equitable access, especially for high-cost therapies targeting small patient populations. Over time, innovative financing mechanisms and stronger patient support services will become essential to sustaining adherence and maximizing therapeutic outcomes.

Continually increasing specialty drug costs will remain a key focus of policymakers, payers and patients. While biosimilar adoption is likely to expand cost savings across the pharmacy- and medical-benefit side, limited uptake for infused biologics and continued growth in gene therapies will keep overall spending elevated. Employers and payers are expected to accelerate use of utilization management and value-based contracts, while policymakers may revisit proposals for Federal negotiation and pricing reform. The tension between innovation and affordability will continue to shape payer strategies, patient access and long-term expansion of the specialty drug market.

Ongoing policy changes will continue to reshape specialty drug pricing and distribution. Federal reforms like the Inflation Reduction Act's cap on Medicare Part D OOP spending and new Medicare Part B coinsurance rules will ease financial pressure for patients but increase cost exposure for manufacturers and payers. The lack of a consistent definition for specialty drugs across programs complicates oversight and benefit design, while the growth of the 340B program raises questions about transparency and whether discounts reach patients. Stakeholders should expect greater scrutiny of drug pricing, increased regulation of distribution models and pressure to demonstrate that savings translate into patient benefit.

Taken together, the specialty drug market sits at the intersection of innovation and sustainability. Stakeholders that align around models which share risk, improve transparency and prioritize patient access will be best positioned to shape a sustainable and effective specialty drug market.

Methodology

To conduct this analysis, secondary data were obtained from a variety of publicly available resources, including peer-reviewed publications and reports from the U.S. Department of Health and Human Services (including Centers for Disease Control and Prevention, Food and Drug Administration and National Center for Health Statistics), Congressional Budget office and pharmaceutical companies.

References

1, 48 Fein AJ, The Top 15 Specialty Pharmacies of 2024, *Drug Channels*, 2025.

2 Assistant Secretary for Planning and Evaluation (ASPE), Trends in Prescription Drug Spending, 2016–2021, *ASPE Issue Brief*, 2022.

3, 16, 17, 27, 28 CarelonRx, Specialty Drug Growth, *CarelonRx Perspectives*, n.d.

4, 51, 53 VPL, How To Stay Competitive in a Growing Specialty Pharmacy Market, n.d.

5 Centers for Disease Control and Prevention, Fast Facts: Health and Economic Costs of Chronic Conditions, 2025.

6 Watson KB, Wiltz JL, Nhim K, Kaufmann RB, Thomas CW, Greenlund KJ, Trends in Multiple Chronic Conditions Among US Adults, by Life Stage, BRFSS, 2013–2023, *Preventing Chronic Disease*, 2025.

7 Pharmko, Specialty Meds for Chronic Conditions, 2025.

8, 20, 21, 22, 25, 29, 30, 43, 44, 45, 55, 56, 67, 68 Szczotka A, Navigating the Rapid Growth of Specialty Drugs: Opportunities, Challenges, and the Path Ahead, *Pharmacy Times*, 2024.

9, 26 U.S. Food and Drug Administration, New Drug Therapy (Novel Drug) Approvals 2025, 2025.

10 U.S. Food and Drug Administration, Rare Diseases at FDA, 2025.

11 Virginia Tech News (Fralin Biomedical Research Institute), One in 10 Americans Is Living With a Rare Disease, 2025.

12 Definitive Healthcare, Most Prescribed Medications for Patients with Rare Diseases, 2025.

13 Magellan Rx Management, Specialty Pharmacy Drug List, 2016.

14 Maldonado R, Jalil S, Wartiovaara K, Curative Gene Therapies for Rare Diseases, *Journal of Community Genetics*, 2021.

15 IQVIA Institute for Human Data Science, The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028, 2024.

18, 19, 32 PSG Consults, 2025 State of Specialty Spend and Trend Report, 2025.

23, 69 What Makes a Drug "Special"? Understanding PBMs' and Pharmacy Definitions, *Health Affairs Forefront*, 2024.

24 KFF (Kaiser Family Foundation), The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019, n.d.

31 Evernorth Research Institute, Pharmacy in Focus: *The Biosimilar Breakthrough in Adoption and Affordability*, 2025.

33 Evernorth, Specialty Pipeline Perspectives: The Upcoming Wave of Biosimilars, 2024.

34 Evernorth, Biosimilars Help Lower Costs and Foster Innovation (Pharmacy Benefits), 2025.

35 Arad N, Staton E, Hamilton Lopez M, Goriola S, Higgins A, McClellan M, Richman B, Realizing the Benefits of Biosimilars: Overcoming Rebate Walls, Duke-Margolis Center for Health Policy, 2022.

36 Bond AM, et al., The Role of Financial Incentives in Biosimilar Uptake in Medicare: Evidence from the 340B Program, *Health Affairs*, 2023.

37, 40 SmithRx, Biosimilar Adoption: Why Low Uptake Is Still a Challenge, 2025.

38 Rieger C, et al., Barriers and Enablers Affecting the Uptake of Biosimilar Medicines (systematic review), *BioDrugs*, 2024.

39 Kwon Y, et al., State Substitution Laws and Uptake of an Interchangeable Biosimilar (cohort study), *JAMA Health Forum*, 2025.

41 Feng et al, Patient Out-of-Pocket Costs for Biologic Drugs After Biosimilar Competition, *JAMA Health Forum*, 2024.

42 U.S. Food and Drug Administration, Approved Cellular and Gene Therapy Products, 2025.

46 Avalere Health Advisory, Specialty Pharmacies Adapt to Support Cell and Gene Therapies, 2024.

47 IPD Analytics, Systemic Gaps Hinder Cell and Gene Therapy Adoption and Access, 2025.

49 Trilliant Health Compass+, Value for Money: How the U.S. Health Economy Can Transition from Maximization to Optimization, 2024.

50 Pipes S, Drugmakers Are Embracing Direct-to-Consumer Sales—That's Fantastic News for Patients, *Forbes*, 2025.

52 Shelley S, Specialty Pharmacy: The Trends Shaping Best Practices, *Pharmaceutical Commerce*, 2024.

54 Centers for Medicare & Medicaid Services, CMS Releases 2025 Medicare Part D Bid Information and Announces Premium Stabilization Demonstration, 2025.

57 The White House, Lowering Drug Prices by Once Again Putting Americans First (Presidential Action), 2025.

58 The White House, Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients (Presidential Action), 2025.

59, 60 McDermott+ Consulting, Trump Administration Executive Order Tracker, 2025.

61 Reuters, Pfizer Does Deal With Trump on Prescription Drug Prices, 2025.

62 Associated Press, AstraZeneca to Cut Medicaid Drug Costs Under Trump Deal, 2025.

63, 66 FiercePharma, Merck KGaA's EMD Serono Strikes MFN Deal Amid Trump's Fertility-Treatment Pricing Push, 2025.

64 The White House, Fact Sheet: President Donald J. Trump Announces First Deal to Bring Most-Favored-Nation Pricing to American Patients, 2025.

65 AstraZeneca, AstraZeneca Announces Historic Agreement With U.S. Government to Lower the Cost of Medicines for American Patients (press release), 2025.

71 Congressional Budget Office, The 340B Drug Pricing Program (report), 2025.

72 Licholai G, FDA and White House Fast-Track Drug Approvals and Innovate on Prices, *Forbes*, 2025.

73 The Commonwealth Fund, New Federal Policies Spur Higher Health Insurance Premiums in 2026: Consumers & Insurer Filings, 2025.