

Drug super spender tsunami: An integrated medical and pharmacy benefits assessment

Catherine I Starner, PharmD, BCPS; Kevin Bowen, MD, MBA; Patrick P Gleason, PharmD, BCPS, FCCP, FMCP

Plain language summary

Drug costs are becoming a larger part of health care spend. Specialty drugs, some with a price exceeding \$250,000 per year per person treated, are increasing. Our findings demonstrate the importance of identifying drug super spenders (ie, >\$250,000/year in drug costs) and the impact they can have. Drug super spenders make up only 32 per 100,000 commercially insured individuals yet represent \$1 of every \$10 dollars spent on drugs. Managing drug super spenders is essential.

Implications for managed care pharmacy

With new drug approvals focused on rare and orphan conditions and with drug therapy costs increasing, drug super spenders, members with greater than \$250,000 in drug costs annually, are growing. It is essential to have insights into the drug super spender conditions and trends. This research shows \$1 of every \$10 spent on drugs is for drug super spenders and growing fast. It is imperative to analyze drug spend through both medical and pharmacy benefits and develop drug super management plans.

Author affiliations

Prime Therapeutics LLC, Eagan, MN (Starner, Bowen, Gleason); Department of Pharmaceutical Care and Health Systems, College of Pharmacy, University of Minnesota, Minneapolis (Starner and Gleason).

AUTHOR CORRESPONDENCE:
Catherine I Starner, 612.777.5073;
cstarner@primetherapeutics.com

J Manag Care Spec Pharm.
2022;28(11):1200-06

Copyright©2022, Academy of Managed Care Pharmacy. All rights reserved.

ABSTRACT

BACKGROUND: As new rare-disease drug therapy, gene therapies, and high-priced cancer drugs receive US Food and Drug Administration approval, there is an increasing potential for drug super spender individuals with more than \$250,000 annual drug cost.

OBJECTIVE: To categorize all members in a large, commercially insured population by their total annual combined drug costs from both medical and pharmacy benefits and to determine the trend in drug super spender prevalence.

METHODS: Using a commercially insured population with integrated medical and pharmacy benefits, all unique members with any enrollment between January 2016 and December 2019 were identified. The sum of total cost for all pharmacy claims plus all medical benefit claim lines for drugs was determined for each member, for each calendar year. Cost was defined as the plan plus member liability at network-discounted price, with no further adjustment for any coupons or rebates. Descriptive statistics were used to describe the drug super spender growth.

RESULTS: There was an average of 17.9 million members per year with at least 1 month of eligibility through the 4-year study period.

In 2016, a total of 2,994 members with more than \$250,000 drug cost per member accounted for \$1,324 million drug spend. In 2019, there were 5,894 super spender members (97% increase), accounting for \$2,579 million drug cost (95% increase), which was 9.6% of \$26,618 million total drug spend.

CONCLUSIONS: In this large, commercially insured population, a small (32 per 100,000) number of drug super spender members comprise a disproportionate portion of the total drug expenditures, at \$1 of every \$10 dollars of total drug expenditures. Health plans need to understand the drug super spender trend and develop strategies to maintain health care affordability.

Overall health care costs, including all private and public spending, are anticipated to rise by an average of 5.5% per year over the next decade, growing from \$3.5 trillion in 2017 to \$6 trillion by 2027.¹ Drug costs are becoming an increasingly large portion of health care. Total drug spend comprises 25% of health care costs among commercially insured individuals when counting drug spend in totality across both medical and pharmacy benefits.² The majority of drug spend comes from specialty drugs, which make up more than 50% of total drug spend.^{3,4} There is no universal definition of specialty drugs. For calendar year 2022, Medicare defined any drug for which the negotiated price is \$830 per month or more as a specialty drug, which is placed in a specialty tier that requires a higher patient cost sharing.⁵ Specialty drugs have an annual cost per therapy of \$84,442 and are used to treat complex, chronic, or rare conditions, such as cancers and inflammatory conditions.^{6,7} Even more underappreciated is that among multiple sclerosis, rheumatoid arthritis, and inflammatory bowel disease drugs can be more than 50% of a member's total cost of care.⁸ Of 50 new drugs approved in 2021, a total of 26 were for rare diseases, and more than half of them have an annual list price of at least \$100,000.⁹ In addition, 1-time (eg, gene) therapies are beginning to enter the market at a cost of more than \$2.1 million.¹⁰ Limited information is available assessing the prevalence and growth in commercially insured members with greater than \$250,000 in annual total drug spend (ie, drug super spenders).

Because of the extreme cost, innovative gene-based therapies and other therapies for rare diseases are a challenge for health care insurers. Health plans are preparing for the impact of these high-cost therapies on total drug spend because 10 or more rare disease gene therapies are expected to be approved annually starting in 2025.¹¹ Total drug management requires integrated medical and pharmacy benefit analytics, predictive modeling, and clinical expertise, combined with robust case management, innovative manufacturer contracting, (eg, value-based purchase arrangements), and fraud, waste, and abuse capabilities. Health plans and pharmacy benefit managers need to understand the drug super spender growth rate and develop strategies to maintain drug access while maintaining health insurance affordability. Equally important factors are ensuring the drug therapy is priced commensurate to the value it provides, utilization of a cost-effective drug delivery channel, and selection of the most cost-effective drug therapy regimen.

The objectives of this analysis were to identify the prevalence of drug super spenders, defined as those with greater than \$250,000 per year in total drug cost, to estimate how the prevalence changed over time, and to evaluate what

proportion of total drug cost came from drug clinical condition categories among the drug super spenders.

Methods

DATA SOURCE

We used medical and pharmacy administrative claims data from 16 commercial health plans representing all regions of the United States with stable membership during the 4 years. The database contained an average of 17.9 million members with any 1 month of eligibility during each calendar year and an average of 9.7 member-months of eligibility per unique member per year to assess prevalence and trends. For study inclusion, we required members to have any period of enrollment between January 2016 and December 2019 and be aged 64 years or younger during the year of analysis. We excluded members older than age 64 years in the year of analysis because of the potential for incomplete data capture among Medicare beneficiaries. The analysis dataset included all medical and pharmacy claims with total paid amounts, defined as a total of plan paid, member paid, and any third-party payment such as supplemental insurance.

For each member, in each calendar year, the sum of total cost was determined for all paid pharmacy claims plus all paid medical benefit drug claim lines. Cost was defined as the plan plus member cost share after network discounts, with no further adjustment for drug manufacturer coupons or rebates. A member was defined as a super spender if total drug cost was greater than \$250,000 in the calendar year. We further categorized members into 3 total drug cost groupings: greater than \$250,000 to \$500,000, greater than \$500,000 to less than \$750,000, and \$750,000 or greater. Drug use for each super spender member was further characterized by drug and drug categories using National Drug Code (NDC) numbers on pharmacy claims and medical claims Healthcare Common Procedural Coding System (HCPCS) codes and NDC numbers when NDC was available. Each drug super spender member was assigned a clinical condition category based on the specialty drug accounting for most of their drug expenditures and the *International Classification of Diseases, Tenth Edition* diagnosis codes on all medical claims incurred for that member during the 4 years, 2016 to 2019. For some clinical conditions, only a single drug was used to define the category, and for others, a large set of drugs was used. For example, nusinersen (Spinraza) was the only drug used in this analysis for spinal muscular atrophy because onasemnogene abeparvovec-xioi (Zolgensma) was not approved until May 2019 and not available until July 2019. Cancer included many different antineoplastic agents and growth-colony stimulating

TABLE 1 Super Spenders Cost Trend, 2016 to 2019, Among an Average 17.9 Million Commercially Insured Members With At Least 1-Month Eligibility

	2016 (N=17,625,170)	2017 (N=17,394,515)	2018 (N=18,221,200)	2019 (N=18,236,336)	2016 to 2019 Change, % (cost; members)
Total drug cost ^a , \$	20,885	21,972	24,555	26,618	↑ 27.5; ↑ 3.5
Total drug cost ^a CPI-U adjusted ^b , \$	22,247	22,917	25,000	26,618	↑ 19.6
Drug super spender ^b , \$ (% total), N (% total)	1,325 (6.3); 2,994 (0.017)	1,617 (7.4); 3,641 (0.021)	2,119 (8.6); 4,869 (0.027)	2,579 (9.7); 5,894 (0.032)	↑ 94.6; ↑ 96.9
>\$250K to \$500K	773 (3.7); 2,317 (0.013)	943 (4.3); 2,838 (0.016)	1,280 (5.2); 3,814 (0.021)	1,542 (5.8); 4,572 (0.025)	↑99.5; ↑ 97.3
>\$500k to <\$750K	254 (1.2); 421 (0.002)	290 (1.3); 489 (0.003)	422 (1.7); 701 (0.004)	519 (2.0); 858 (0.005)	↑104.3; ↑ 103.8
≥\$750K	297 (1.4); 256 (0.001)	384 (1.7); 314 (0.002)	417 (1.7); 354 (0.002)	517 (1.9); 464 (0.003)	↑74.1; ↑ 81.3
Drug super spender CPI-U adjusted ^{b,c} , \$	1,411	1,687	2,626	2,579	↑82.7

All costs displayed in millions (US dollars).

^aAll drug expenditures through the medical and pharmacy benefit, including network discounts, plan allowed amount, and member share. Pharmaceutical rebate discounts or coupons not included.

^bIndividuals with greater than \$250,000 in annual drug cost through medical and pharmacy benefits.

^cAdjusted to 2019 US dollars.¹²

CPI-U=consumer price index–urban.

factor drugs like pegfilgrastim (Neulasta). Cystic fibrosis included disease-modifying agents, inhaled antibacterials, and pancreatic enzymes. Descriptive statistics were used to describe growth in the number of super spenders and their aggregate expense and to subcategorize these trends by clinical condition categories. Inflation adjustment was done using the consumer price index for all urban customers.¹²

Results

As shown in Table 1, in 2016, among 17.6 million commercially insured members with at least 1 month of eligibility, there were 2,994 (0.017% of all members) drug super spender members, accounting for \$1,325 million drug spend, which was 6.3% of all drug spend. As shown in Table 2 for these 2,994 members, clinical condition-specific drug spend accounted for 95% (\$1,262 million) of all their drug spend. In 2017, super spenders increased to 3,641 (0.021%) of 17.4 million members, accounting for \$1,617 million (7.4% of all drug spend). In 2018, a total of 4,869 (0.0275%) of 18.2 million members accounted for \$2,119 million (8.6% of all drug spend). In 2019, super spenders increased to 5,894 (0.032%) of 18.2 million members, accounting for \$2,579 million (9.7% of all drug spend). For these 5,894 members, clinical condition-specific drug costs accounted for 98% (\$2,527 million) of their total drug spend. The vast majority of drug super spenders' drug costs are accounted for by drugs to treat

clinical conditions found in Table 2, with 95% of all drug super spender drug costs in 2016 and increasing 3 percentage points to 98% in 2019.

From 2016 to 2019, membership increased 3.5%, were as drug super spenders increased 97%, and their drug costs increased 95%, whereas the entire membership drug costs increased 27.5%. Drug spend increased 3.5 times faster among drug super spenders, with a \$1,264 million increase in clinical condition-specific drug costs. As shown in Table 1, inflation-adjusted all-membership drug costs from 2016 to 2019 increased 19.6%, and the super spender drug costs increased 82.7%; 4.2 times faster among drug super spenders.

The cancer clinical condition drug spend increased 153%, from \$432 million in 2016 to \$1,094 million in 2019. The increase in cancer drug spend accounted for 53% of the total \$1,254 million super spender drug spend increase. The largest cancer increases occurred within specialty drugs to treat breast cancer (\$135 million), multiple myeloma (\$126 million), and lung cancer (\$125 million). Inherited single-gene disorders drug therapy accounted for \$377 million (30%) of the total super spender drug spend increase, of which hemophilia A and B drug therapy accounted for 24.9% of the 2019 total drug spend in the category. Disorders treated with complement inhibitors was one of the fastest growing expenditure drug super spender categories consisting of 1 drug, eculizumab (Soliris), which

TABLE 2 Drug Super Spenders From 2016 to 2019 by Drug Therapy Clinical Condition Categories

Clinical condition drug-specific utilizers and drug costs	Super spender members, N		Medical plus pharmacy claims cost for super spender members' drugs to treat condition, \$ (in millions)		
	Year 2016	Year 2019	Year 2016	Year 2019	Change from 2016 to 2019
Cancer	1,141	2,776	431.6	1,094.0	662.4
Breast	259	575	96.8	231.9	135.1
Lung	117	378	43.2	168.3	125.2
Multiple myeloma	112	456	37.2	163.4	126.2
Melanoma	134	198	60.9	84.7	23.7
Non-Hodgkin lymphoma	76	159	27.4	62.0	34.5
Colorectal	104	156	41.1	61.3	20.2
Kidney	28	161	9.2	60.5	51.4
Malignant neuroendocrine	30	102	9.8	43.0	33.2
Acute lymphoblastic leukemia	51	62	26.9	29.8	2.8
Ovary	27	65	10.3	24.7	14.4
Hodgkin disease	27	58	10.0	24.7	14.7
Prostate	35	44	9.5	16.8	7.4
Other cancer	141	362	49.3	132.8	83.5
Inherited single-gene disorders	878	1,770	435.3	812.4	377.1
Hemophilia A	229	347	128.8	202.6	73.8
Cystic fibrosis	205	550	64.6	193.3	128.7
Hereditary angioedema	97	127	63.8	77.6	13.8
Spinal muscular atrophy	-	115	0.0	65.2	65.2
Hemophilia B	52	68	27.7	45.4	17.7
Fabry disease	52	67	20.8	26.8	6.0
Congenital hypophosphatasia	13	20	10.1	24.7	14.6
Pompe disease	22	30	18.4	24.5	6.1
Gaucher disease	50	54	20.8	24.5	3.7
Mucopolysaccharidoses	31	29	20.6	18.9	(1.6)
Urea cycle disorders	9	21	5.6	13.6	7.9
Cystinosis	15	19	7.1	11.8	4.7
Chronic granulomatous disease	21	16	9.3	9.8	0.6
Gout	4	22	1.7	9.2	7.6
Duchenne muscular dystrophy	-	8	0.0	7.5	7.5
Other single-gene disorders	78	133	36.1	56.9	20.8

continued on next page

expanded its US Food and Drug Administration (FDA)-approved indication during the 4-year analysis period to include hemolytic-uremic syndrome, paroxysmal nocturnal hemoglobinuria, and myasthenia gravis. Drug costs for 1 condition category, cystic fibrosis, increased 199% over

the 4-year period because of 2 new drugs. The number of unique members in the highest cost band, \$750,000 or more per year, was 256 in 2016 and 464 in 2019 (81% increase), with their total drug cost increasing from \$297 million in 2016 to \$517 million in 2019 (74% increase).

TABLE 2 Drug Super Spenders From 2016 to 2019 by Drug Therapy Clinical Condition Categories (continued)

Clinical condition drug-specific utilizers and drug costs	Super spender members, N		Medical plus pharmacy claims cost for super spender members' drugs to treat condition, \$ (in millions)		
	Year 2016	Year 2019	Year 2016	Year 2019	Change from 2016 to 2019
End-stage renal disease	370	453	143.0	184.6	41.6
Autoimmune disorders	195	467	73.1	163.8	90.7
Inflammatory bowel disease	43	166	15.6	50.5	34.9
Multiple sclerosis	47	103	16.7	38.5	21.7
Chronic inflammatory demyelinating polyneuritis	34	59	13.6	22.7	9.1
Other	71	139	27.2	52.1	25.0
Disorders treated with complement inhibitors	104	190	75.2	139.9	64.7
Hemolytic-uremic syndrome	55	80	44.4	68.4	24.1
Paroxysmal nocturnal hemoglobinuria	49	64	30.8	39.9	9.1
Myasthenia gravis	–	46	0.0	31.5	31.5
Pulmonary hypertension	88	189	26.9	67.6	40.8
Cushing syndrome	7	32	2.3	12.9	10.6
Immunoglobulins	13	23	13.7	9.8	(3.9)
Hepatitis C	76	–	22.5	0.0	(22.5)
All others	122	138	38.6	41.6	3.0
Total clinical condition–category drugs	2,994	5,894	1,262.1	2,526.7	1,264.5
Total all medical plus pharmacy drugs	2,994	5,894	1,324.5	2,578.7	1,254.2

Drug super spenders are defined as individual members with greater than \$250,000 in pharmacy plus medical drug cost per year. Cost is defined as the plan plus member cost share after network discounts, with no further adjustment for drug manufacturer coupons or rebates. Drug indication category is the clinical condition for high drug cost deduced from a combination of information from the specific drugs accounting for most of the member's drug expense and International Classification of Diseases, Tenth Revision diagnosis codes on all medical claims. Specified drugs are a set of specific specialty drugs for each condition category derived from preliminary exploratory analysis: Mucopolysaccharoidoses (mucopolysaccharoidosis 1, 2, 4a, 6, and 7 combined) and; complement inhibitors (eculizumab [Soliris] and ravulizumab [Ultomiris]). Total all medical plus pharmacy drugs is the sum of expense for specified specialty drugs and all other drugs for drug super spenders. Bold values are an overall count of the rows below them.

Discussion

In this large, commercially insured population with integrated medical and pharmacy benefits, members with more than \$250,000 in annual drug cost across both medical and pharmacy benefits doubled from 2016 to 2019, creating a potential tsunami of continued cost growth as these drug super spenders, although rare at 32 per 100,000, had more than \$2.6 billion in drug cost, accounting for \$1 of every \$10 in total drug cost, among 18 million members. Cancer drug category was a major driver of the spend increase within drug super spenders, accounting for more than half of the total drug cost increase over 4 years, consistent with national data showing oncology as a major portion of drug spend.⁶ More than one-third of super spender drug expense is through the pharmacy benefit, remaining stable from 2016 at 34.2% to 2019 at 34.7%, reflecting the current dominance

of cancer drug therapies that are primarily billed through the medical benefit. Cancer drug therapies comprised 42% of drug super spender expense in 2019. If this and other trends continue over the next 5 years, we forecast drug super spenders will account for more than 15% of the total combined drug spend through the medical and pharmacy benefits among all commercially insured members.

Extraordinarily high drug expense (ie, drug super spenders) can result from a variety of different factors acting alone or in combination. Use of drugs for which manufacturers have set high prices is a common factor. In some cases, contractual agreements play an important role, such as agreement by a health plan to pay a percentage of charges for medical claims by a facility combined with the facility's decisions about what to charge.

Although pharmaceutical innovation is bringing needed therapies to market, these new therapies are creating more drug super spenders. Orphan drugs are a fast-growing

segment of the drug development market and drug super spender growth.⁶ In 2019, the most recent year of this analysis, orphan drugs sales were \$58 billion and accounted for 11% of overall prescription drug sales. Orphan drug sales have grown 14% per year for the past 5 years.⁶ From 2020 to 2021, 47% of newly approved drugs were initially priced above \$150,000 per year, and the orphan drug median price per-year change from 2008 to 2021 was a \$168,344 increase.¹³ By 2025, the FDA may be approving 10-20 cell and gene therapy products annually, and at prices in the mid \$100,000s to low millions, health insurers will need to be prepared for these added costs.^{11,14}

Health insurers have little to no negotiating power to obtain orphan drug cost concessions from manufacturers. Options include requiring manufacturer coupon and patient assistance program maximization, higher member out-of-pocket costs, setting quantity limits, prior authorization, medical policy review, and using step therapy. However, in rare disease, these options may not be ideal or effective. Instead, planning for sudden, catastrophic extreme costs of expensive therapies while preserving access and affordable drug therapy is the goal. Ensuring access and affordability has 3 parts: Forecasting potential utilization and costs, care management programs with drug therapy regimen optimization assessment and monitoring, and financial payment. One strategy is to look at drug therapy holistically across both medical and pharmacy benefits to forecast potential utilization and costs, as well as perform ongoing drug therapy regimen optimization assessments. With integrated health insurer and pharmacy benefit manager services, a managed care pharmacist and a dedicated data science team can provide ongoing drug therapy

regimen assessment, working in collaboration with the health plan and the member's providers to ensure drug therapy optimization and cost-effectiveness. For example, they can advocate for the use of generics and biosimilars and for vial size optimization to avoid drug waste, assess for self-administration options where appropriate, optimize dosing based on weight or dispensing of medication in the provider office, and monitor and resolve inappropriate duplicate therapy. Integrated within the health plan, managed care pharmacists may also have access to patient-specific elements outside of claims data that could lead to other cost-saving interventions as well, including help to ensure the lowest cost share for the member and maximization of all discounts available (eg, pharmaceutical manufacturer coupons and patient assistance programs).

Within the financial component, value-based purchase arrangements (VBPA) with pharmaceutical manufacturers have grown rapidly over the past few years.^{15,16,17} Value-based contracts are arrangements that connect drug payment to outcomes. The VBPA can act as a guarantee that if a drug does not work as expected, the manufacturer will refund some or all the drug's cost to the plan.¹⁷ However, VBPA have barriers that need to be overcome. One area of concern is who will track the outcomes and what happens if the company is due a reimbursement for a member who has since moved to another health plan.¹⁸ Another issue is related to the "best price" requirement of the Medicaid Drug Rebate Program, for which Centers for Medicare & Medicaid Services has proposed modifications, increasing flexibility and encouraging value-based arrangements to avoid drastically lower best price.¹⁵

LIMITATIONS

This analysis has limitations. First, although the data were from a large population, many of the individual conditions described are too rare to accurately estimate prevalence for comparisons to national prevalence rates. Second, the results represent commercially insured lives from many different clients of a national pharmacy benefit manager. The findings cannot be extrapolated to populations such as Medicare or Medicaid and may differ from other commercially insured populations with different attributes, such as commercially insured members aged 65 years and older, as this analysis excluded those older than 64 years. Third, our drug cost amounts are the sum of plan plus member payments after network discounts, with no further adjustment for drug manufacturer coupons or rebates. However, rebates for drugs to treat the clinical conditions listed in Table 2 are uncommon, except for autoimmune disorders, immunoglobulins, and hepatitis C.

Conclusions

In this large, commercially insured population, a small (32 per 100,000) number of drug super spender members with more than \$250,000 drug spend in 1 year comprise a disproportionate portion of the total drug expenditures, at \$1 of every \$10 dollars of total drug expenditures. Drug super spenders doubled from 2016 to 2019, along with their drug expenditures. Health plans need to understand the drug super spender trend and develop strategies to maintain health care affordability.

DISCLOSURES

This study was funded internally by Prime Therapeutics LLC. Drs Starner and Gleason are employees of Prime Therapeutics LLC, a pharmacy benefits management company. Dr Bowen is a former employee of Prime Therapeutics LLC.

REFERENCES

- Peter G Peterson Foundation. Healthcare costs for Americans projected to grow at an alarmingly high rate. 2019. Accessed August 8, 2022. <https://www.pgpf.org/blog/2019/05/healthcare-costs-for-americans-projected-to-grow-at-an-alarmingly-high-rate>
- Sherman M, Curfman GD, Parent J, Wagner AK. Prescription medications account for one in four dollars spent by a commercial health plan. *Health Affairs*. 2018. Accessed March 21, 2022. <https://www.healthaffairs.org/doi/10.1377/forefront.20180821.820628/full/>
- Hill SC, Miller GE, Ding Y. Net spending on retail specialty drugs grew rapidly, especially for private insurance and Medicare Part D. *Health Aff (Millwood)*. 2020;39(11):1970-6. doi:10.1377/hlthaff.2019.01830
- Certara. Key trends in US specialty pharmacy: Payer perspectives and developer strategies, 2020-23. Certara. Accessed August 8, 2022. <https://www.certara.com/app/uploads/2020/09/Key-Trends-in-US-Specialty-Pharmacy-email.pdf>
- Avalere. What to watch for in MA and Part D contracting for the 2022 plan year. 2021. Accessed March 21, 2022. <https://avalere.com/insights/what-to-watch-for-in-ma-and-part-d-contracting-for-the-2022-plan-year>
- IQVIA Institute for Human Data Science. Orphan drugs in the United States rare disease innovation and cost trends through 2019. 2020. Accessed August 8, 2022. <https://www.iqvia.com/insights/the-iqvia-institute/reports/orphan-drugs-in-the-united-states-rare-disease-innovation-and-cost-trends-through-2019>
- Schondelmeyer S and Pervis L. Trends in retail prices of specialty prescription drugs widely used by older Americans, 2006 to 2020. AARP Public Policy Institute. 2021. Accessed August 8, 2022. <https://www.aarp.org/content/dam/aarp/ppi/2021/09/trends-retail-prices-specialty-drugs>. doi:10.26419-2Fppi.00073.006.pdf
- Gleason PP, Alexander GC, Starner CI, et al. Health plan utilization and costs of specialty drugs within four chronic conditions. *J Manag Care Pharm*. 2013;19(7):542-8. doi:10.18553/jmcp.2013.19.7.542
- US Food & Drug Administration. Advancing health through innovation: New drug therapy approvals 2021. Accessed March 15, 2022. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021>
- Stein R. At \$2.1 million, new gene therapy is the most expensive drug ever. NPR. May 24, 2019. Accessed August 12, 2022. <https://www.npr.org/sections/health-shots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever>
- Gotlieb S. Statement from FDA Commissioner Scott Gottlieb, MD and Peter Marks, MD, PhD, Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies. US Food & Drug Administration. 2019. Accessed August 8, 2022. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics>
- US Bureau of Labor Statistics. Consumer price index. Accessed August 8, 2022. <https://www.bls.gov/cpi/tables/supplemental-files/home.htm> (in the January 2022 historical CPI-U, January 2022 database link)
- Rome BN, Egilman AC, Kesselheim AS. Trends in prescription drug launch prices, 2008-2021. *JAMA*. 2022;327(21):2145-7. doi:10.1001/jama.2022.5542
- Shukla V, Seoane-Vazquez E, Fawaz S, Brown L, Rodriguez-Monguio R. The landscape of cellular and gene therapy products: Authorization, discontinuations, and costs. *Hum Gene Ther Clin Dev*. 2019;30(3):102-13. doi:10.1089/humc.2018.201
- Centers for Medicare & Medicaid Services. Establishing minimum standards in Medicaid state Drug Utilization Review (DUR) and supporting value-based purchasing (VBP) for drugs covered in Medicaid, revising Medicaid Drug Rebate and third party liability (TPL) requirements (CMS 2482-P) Fact Sheet. June 17, 2020. Accessed August 8, 2022. <https://www.cms.gov/newsroom/fact-sheets/establishing-minimum-standards-medicaid-state-drug-utilization-review-dur-and-supporting-value-based>
- Verma S, Coster J, Guram J. Value-based purchasing rule for medicaid Rx drugs: Continuing to shift from FFS towards accountability. *Health Affairs*. 2021. Accessed August 8, 2022. <https://www.healthaffairs.org/doi/10.1377/forefront.20210119.109892>
- Kelsey Waddill. 12% Of payers implemented 10 or more outcomes-based contracts. *Health Payer Intelligence*. 2021. Accessed August 8, 2022. <https://healthpayerintelligence.com/news/12-of-payers-implement-10-or-more-outcomes-based-contracts>
- Alison McCook. 'Super spenders' skyrocketing. Specialty Pharmacy Continuum. 2019. Copyright © 2004-2019 McMahon Publishing. Specialty Pharmacy Continuum and SpecialtyPharmacyContinuum.com are part of McMahon Publishing. Accessed August 8, 2022. <https://www.specialtypharmacycontinuum.com/Policy/Article/12-19/-Super-Spenders-Skyrocketing/56547>