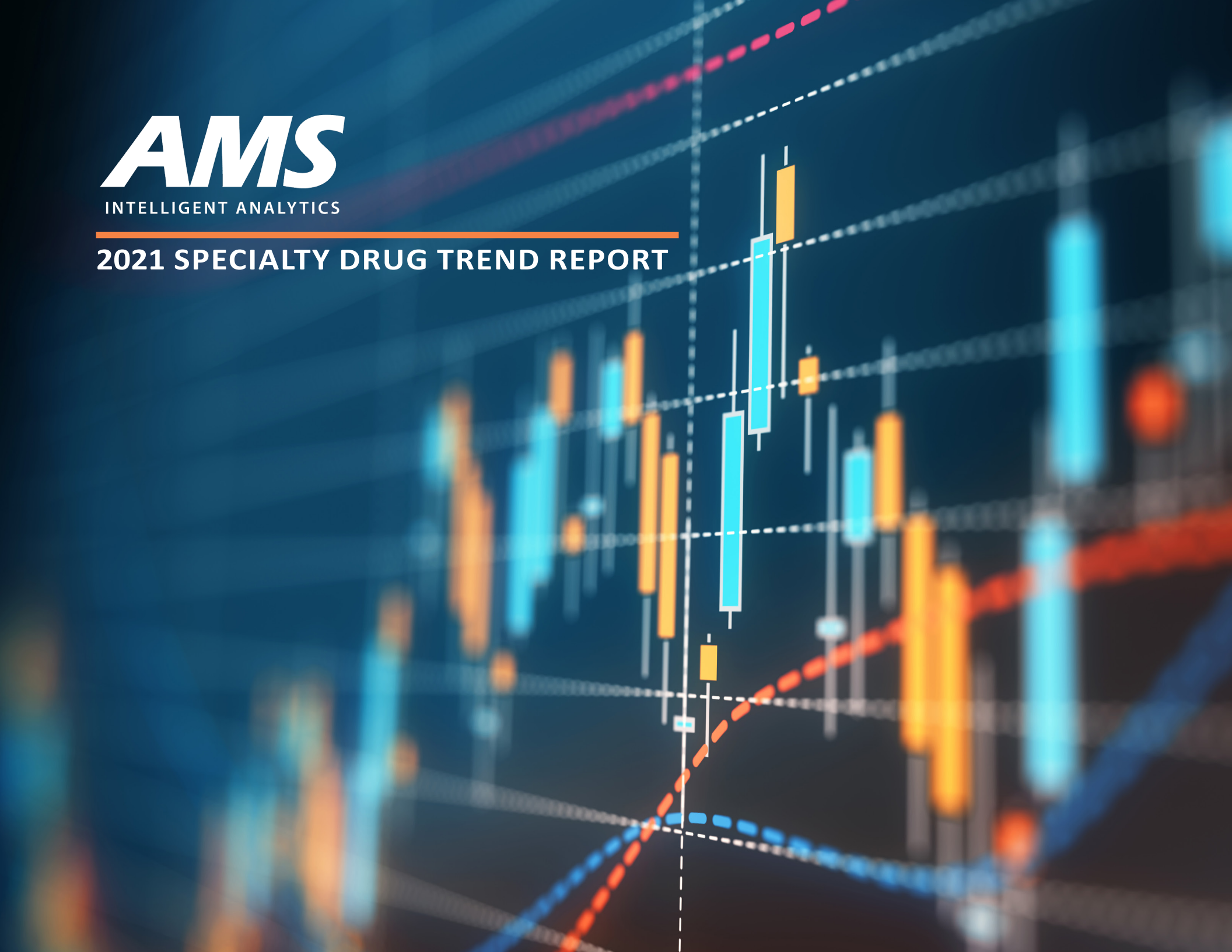
AMS
INTELLIGENT ANALYTICS
2021 SPECIALTY DRUG TREND REPORT

By the Numbers

- 51% ..... Specialty drugs accounted for more than half of total drug spend
- 3.37% ... Projected specialty drug price inflation rate
- 75% ..... Percentage of specialty drugs among the approximately 7,000 prescription drugs currently in development
- 50 ..... Total FDA-approved drugs in 2021; 26 Orphans
- 29 ..... Specialty drugs added to PredictRx in 2021; 20 Orphans

Looking back from Year 3 of the ongoing coronavirus pandemic, the biggest news of 2021 was undoubtedly that the FDA approved BioNTech's mRNA vaccine Comirnaty (tozinameran). BioNTech, later partnering with Pfizer, began working on the vaccine for COVID-19 in January of 2020. That July, Phase II/III trials were underway and by December enough safety and efficacy data was presented to the FDA for an emergency use authorization (EUA).

On August 23, 2021, based on results from the clinical trial in which the vaccine was 91% effective in preventing COVID-19 disease, the FDA gave its full approval—less than two years after the program started.[1] (A typical timeline for developing a vaccine is about seven years, though BioNTech developers did have a head start: it was not an unfamiliar technology since progress had already been made on the original SARS and MERS virus outbreaks.) [2]

As the year drew to a close, 73.5% of the US population had received at least one dose of a vaccine. But by then COVID was the third leading cause of death, trailing heart disease and cancer—both of those encompassing a wide variety of distinct diseases. By the CDC's estimation there were approximately 460,000 COVID-related deaths in the US during 2021. Improbably, more than 60% of the now 1+ million US deaths have occurred since vaccines came onto the market. And life expectancy fell by two years.

Also stemming from COVID-19 was a disruption of the top drugs by total spend. In pre-pandemic years the pharmaceuticals placing highest on the list were all familiar faces: Humira, Keytruda, Stelara, Ocrevus, Remicade, Opdivo. Vaulting onto the list as the top-ranked medication in recent years has been Veklury (remdesivir), a first-line treatment for COVID-19. Altogether they have one thing in common: they're all specialty drugs.

Drug Spend

While less than 2% of the population uses specialty drugs, they now account for about 55% of total pharmacy spending per IQVIA.[3] That same report states that "the rise in specialty spending has been predominately driven by autoimmune diseases and oncology, where spending has increased 459% and 226% respectively since 2011 on a net basis." The actual 2021 percentage may have been slightly lower because of the pandemic affecting the projections; however, as we transition out of it and into "normalcy" many payers are seeing specialty costs climb upwards to 60% or an even higher proportion of their total drug spending.[4] Payers are feeling the pain since it purportedly costs 75x more to cover a specialty patient over the course of a year than a non-specialty patient.

Last year's report listed some bullet points regarding branded and generic drug statistics that bear repeating:

- Generic drugs and biosimilars account for 90% of all prescriptions filled
- The remaining 10% of prescriptions contribute to over 80% of all prescription drug spending
- Spending on the 20 largest selling branded drugs in 2018 was greater than the total sales of all generic drugs: $109 billion versus $103 billion[5]

Per AARP, between 2019 and 2020, retail prices for 180 widely used specialty prescription drugs increased by an average of 4.8%, more than three-and-a-half times higher than the general inflation rate of 1.3%.[6] In the same report, AARP researched the retail price for 88 widely prescribed specialty drugs taken by older Americans for treating chronic conditions. As the title from following graphic plainly—and alarmingly—shows, in a mere 15 years the average price of specialty drugs has quintupled.

The Average Annual Price of Specialty Drugs Quintupled between 2006 and 2020

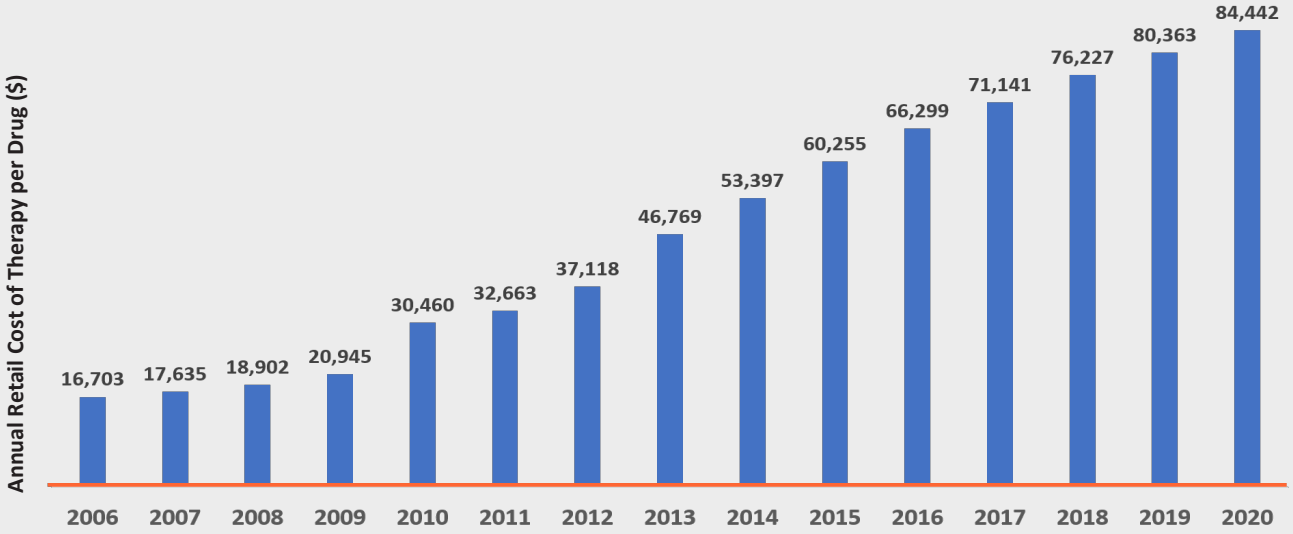

Figure 1

NOTE: Calculations of the average annual specialty drug price change include the 88 drug products most widely used by older Americans for chronic conditions.
Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from IBM MarketScan Research Databases.

The growth has slowed in recent years and may continue to do so as major specialty drugs have impending loss of exclusivity (LOE). The FDA prioritizes reviews of what they call "first generic drugs," that is, new generics to brands which previously had no competition. For 2021, the most notable specialty drugs with LOE (aka going off-patent) were Sutent, Feraheme, and Carbaglu. All three had first generics launch that same year.

- Sutent | Treatment of Gastrointestinal and Pancreatic Tumors; Renal Cell Carcinoma: 2020 US sales: $223 million; ART: $350-490k per year [a]
- Feraheme | Treatment of Iron Deficiency Anemia: 2020 US sales: $150 million (estimate); ART: $4,000 per year
- Carbaglu | Treatment of NAGS (N-acetylglutamate synthase) Enzyme Deficiency (Urea Cycle Disorder): 2020 US sales: $124 million (estimate); ART: $6.5M per year

Other 2021 LOE drugs were Otezla, Sprycel, Cerdelga, Xtandi, and Xeljanz, though generic competition for those have not yet entered the marketplace. Looking forward, Actemra, Alimta, Abraxane, Velcade, and Revlimid all have anticipated 2022 LOE dates. And, of course, specialty biologic behemoths Humira and Stelara will finally see biosimilar competition launch in 2023.

The introduction of oncology biosimilars has reduced the growth rate in oncology spending by approximately 50% since 2019, contributing to a total $18 billion saved on oncology medication in 2020.[7]

Drug prices only increased 1.9% in 2021, in part thanks to new biosimilars and generics that came to market. Total drug spending in the U.S. grew 7.7% in 2021 to $576.9 billion. Hospitals accounted for $39.6 billion, with 8.4% growth over 2020, and clinics accounted $105 billion in spending, a 7.7% increase. Higher utilization and new drugs drove spending growth.[8]

Despite all the good news regarding generics and biosimilars, the drug price inflation rate for specialty drugs is estimated to be between 3.37% and 4.8%. Specialty drug utilization, according to a Seagal report, was forecast to be 8.1% in 2021.[9]

[a] ART represents a fiscal red line of cost tolerance. ART is the absolute maximum specialists should tolerate as billed on a claim. Anything approaching—and certainly beyond—this price threshold should be reviewed for additional cost containment. Additionally, in an underwriting/lasering scenario where one has little to no information at hand (other than the patient will be receiving this drug) the ART is a conservative estimate of what the drug will cost.

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Overall, the average net price of a prescription—the cost after discounts and rebates given to private insurers and federal programs—fell from $57 in 2009 to $50 in 2018 in the Medicare Part D program and from $63 to $48 in the Medicaid program, according to the Congressional Budget Office's (CBO) latest prescription drug spending, use, and pricing report. That partially reflects the increased use and falling average price of generic drugs. However, the average net price of brand-name drugs skyrocketed in that time frame, rising from $149 to $353 in Medicare Part D and from $147 to $218 in Medicaid."[10]

The CBO estimated that after accounting for rising rebates, Medicare Part D reimbursement for brand-name drugs increased by 4% every year from 2011 to 2015. That rise is in line with a study published in JAMA.[11] The study authors found that from 2007 to 2018 branded drug net prices for Medicaid and non-Medicaid payers increased every year by an average of 4.5 percentage points, or 3.5 times faster than inflation.

More recently, according to research firm GlobalData, branded drug prices fell an average of 2% to 9% per year between 2017 and 2021 in five of the six largest pharmaceutical markets—Japan, Germany, Australia, Spain, and France. During the same timeframe in the US, list prices for patented drugs increased by an average of 18% per year.[12]

This puts unbelievable pressure on patients who rely on these lifesaving medications. Vanderbilt University Medical Center researchers found that, in 2021, more than 70% of Medicare Part D beneficiaries did not qualify for low-income subsidies and thus faced steep specialty drug costs. In fact, the authors found that among patients without subsidies: 30% did not fill their prescribed cancer treatments; 22% did not fill curative treatments for hepatitis C; and more than 50% did not fill disease-modifying therapies for immune disorders.[13] Heartbreaking news.

70%

Percent of Medicare Part D beneficiaries did not qualify for low-income subsidies in 2021.

- Vanderbilt University Medical Center -

Specialty pharmacies provide medications used to treat rare, chronic, or complex health problems. An AHIP report [14] looked at drug price hikes (2018-2020) that hospitals and physician offices charge over and above what can be purchased by "white-bagging" from specialty pharmacies. Hospitals, on average, charged double (108%) the prices for the same drugs, compared to pharmacies. The top three: Herceptin, Remicade, and Opdivo. By comparison, physician offices only charged 22% higher prices for the same drugs, on average. Among the highest: Herceptin, Tecentriq, and Keytruda.

Pharmaceutical companies and insurers, working with third parties called pharmacy benefit managers (PBMs), arrange confidential rebates that reduce the net price of the drug to insurers.[15] For 2021, brand-name drugs' net prices dropped for the fourth consecutive year.[16] Yet rebates rarely reduce the costs for the people buying medications. Insurance may cover a particular medication, but since a patient's co-pay is based on the original manufacturers' price—and not the lower, negotiated cost paid by the PBM—the patient ends up paying more.[17] From a broader perspective, a research team from the National Bureau of Economic Research found that while drug copay coupons do save patients on prescriptions, they increase amounts paid by insurers and employers considerably. By way of example, coupons raise negotiated prices by 8% and increase US healthcare spending by roughly $1 billion annually—for multiple sclerosis drugs alone.[18] This is the topsy-turvy world of drug pricing as we know it. **The Ohio non-profit drug pricing data watchdog, 46brooklyn, harshly dubs prescription drug rebates as "money from sick people."**

The disconnect is astonishing. From the manufacturers' perspective drug net prices—especially for traditional drugs and generics—are going down. That's not what payers are seeing, though, "since PBMs, insurers, and these newer rebate GPOs aren't obligated to pass through all those drugmaker concessions," according to Antonio Ciaccia, CEO of 46brooklyn. "Additionally, with launch prices being a greater emphasis point, it distorts the conversation around rebate vs list growth over time." [19]

So, while it is true that the number of significant price increases is trending down, the average launch price of new drugs is simultaneously rising.

According to another recent JAMA report[20] specifically focused on prescription launch prices:

> **"From 2008 to 2021, launch prices [based on WAC, or list prices] for new drugs increased exponentially by 20% per year.** In 2020-2021, 47% of new drugs were initially priced above $150,000 per year. Prices increased by 13% per year even after adjusting for estimated manufacturer discounts and changes in certain drug characteristics, such as more oncology and specialty drugs (e.g., injectables, biologics) introduced in recent years … The trend in prices for new drugs outpaces growth in prices for other healthcare services."

Those exorbitant launch prices preclude the need for yearly double-digit spikes that frequently occurred before the unofficial 9.9% price hike ceiling came into effect. Nevertheless, Big Pharma does routinely increase their prices subsequent to launch and, despite verbal pledges to the contrary, drug manufacturers like Merck and Amgen have raised their prices exceeding that 9.9% ceiling in recent years.

"When you think about launches and development…the innovation is not really in traditional pharmaceutical products anymore," says Doug Long of IQVIA. "It's in specialty, it's in orphan drugs, it's in monoclonal antibodies, it's in cell and gene therapies. And all of these things are expensive products [with a] very small patient population."[21] With regard to coupons as discussed above, frankly, specialty drugs really don't factor into the equation anyway: seldom do these high-dollar drugs with limited competition offer significant manufacturer rebates.

In last year's report we stated that "Big Pharma has completely changed their pricing strategy" regarding launch pricing for new drugs. Historically, a drug would be priced at a reasonable mark-up beyond the cost to manufacture and market the product. Now, it is seemingly whatever profit they think they can get away with. Our conclusions also dovetail with health economist and Fuqua strategy professor, David Ridley, who co-authored research published in The Review of Economics and Statistics: "So long as Medicare reimburses providers based on cost, costs will continue to rise and taxpayer dollars will be wasted." His research concurs that "the current policy also induces firms to front-load their launch pricing—beyond even the profit-maximizing price—in order to win higher reimbursement for providers." [22]

Moreover, **where novel drugs once either proffered a modicum of benefit along with lower costs or demonstrated improved quality of life (or both), those tenets don't necessarily apply anymore.** The FDA's rejection of their own advisors in approving Aduhelm (aducanumab-avwa) for the treatment of Alzheimer's disease is a perfect example of this. The drug's efficacy is questionable at best, with experts projecting annual cost of $10 billion just for Medicare—equal to the top five drugs (Keytruda, Eylea, Opdivo, Rituxan and Prolia) in Medicare combined. Those devastating spending impacts were entirely plausible until a CMS decision narrowed its accelerated approval only for Alzheimer's disease patients enrolled in qualifying clinical trials, curtailing coverage from approximately 1.5 million potential Alzheimer's patients to a mere few thousand.[23] Regardless, it opened the proverbial Pandora's Box of other expensive, ineffectual drugs being approved by the FDA simply on the potential of benefit and/or public pressure in getting a treatment to market in order to fill a void, no matter its proven value—e.g., Amylyx's pending ALS candidate submission. [24]

At the time, some believed that Aduhelm would be the drug that will finally spur changes in current US health policy issues. With its dubious clinical effectiveness and an excessively broad label it did seem like the poster child for drug pricing reform. (Indeed, persistent calls from industry experts for the FDA to withdraw its approval coupled with its own poor sales figures due in no small part to major university-affiliated hospitals refusing to prescribe the drug[25] spurred manufacturer Biogen to announce that it would cut its price by approximately 50% starting January 2022—resulting in an annual ACP[b] reduction of $91,204 in 4Q2021 to $83,398 in 1Q2022, but still a far cry from independent cost watchdog ICER's estimated cost-effectiveness of roughly $5,000/year). However, we've been down this road before. Healthcare pundits spoke of Daraprim, Sovaldi, and Zolgensma as drugs that would break the camel's back.[26] And yet, the status quo remains: **meaningful drug legislation remains elusive, Medicare price negotiation talks are stalled, and novel drug prices trend ever upward.**

Not that the new administration isn't without allies. Joining forces against Big Pharma in the prescription price fight is the AARP, spending massive amounts (yet still about a third that PhRMA doled out) in 2021 on lobbying efforts. The Campaign for Sustainable Rx Pricing coalition also entered the fray, coughing up major dough to protect the interests of insurers and PBMs.[27] Though these are some powerful combatants presumably playing for the "good guys" it remains difficult to be optimistic that drug prices will come down anytime soon.

While the government's struggles with cost containment for drugs continued in 2021, there was significant movement towards price transparency. An interim final rule issued by the Biden administration requires private insurers to report prescription drug costs to the federal government:

> "Each year, insurers will be asked to provide information such as the 50 most frequently dispensed brand drugs, the 50 costliest drugs based on total spending and the 50 drugs with the largest increase in plan or coverage expenditures year over year. Insurers will also be required to submit data on rebates, fees and other remuneration paid by drug companies to the plan in each therapeutic class, as well as the 25 products that yielded the highest amount of rebates. They must also include information on the impact rebates have on premiums and out-of-pocket costs."[28]

[b] This AMS Proprietary benchmark is calculated using federally contracted rates for government agencies, incorporating amounts paid by any private-sector purchaser for the pharmaceutical. Discounts, rebates, chargebacks, and other fiscal adjustments are all factored into the price. Simply put, ACP is the expected cost for a particular drug dosage amount.

It is expected that the first report will be released by the Centers for Medicare & Medicaid Services (CMS) mid-2023.

The above was not the government's only foray into price transparency. Hospital price increases—which include prescription drugs—have been escalating for years with little insight into how or why this was occurring. Over the years, hospital systems continued to tell the general public that their mergers and consolidations would benefit their communities by driving costs down. Usually, though, the opposite happened as the larger entities obtained greater bargaining power via market domination and ultimately increased their prices. Prices, mind you, which remained opaque.

For this reason, according to survey respondents in annual Segal reports, "Using Healthcare Transparency Tools" has consistently ranked near the top of Health Plans' top cost-management strategies.[29] Which is why the government stepped in. **January of 2021 was the start date of the CMS' Hospital Price Transparency Rule requiring hospitals to make their chargemaster prices available online.** Two of the rule's main requirements are 1) to be a comprehensive, machine-readable file (MRF) including "all items and services" provided by the hospital; and 2) to provide the public with 300 consumer-friendly shoppable services offered by the hospital. In short, the new transparency rules were expected to put downward pressure on prices with the aim of reducing spend for payers looking to use that chargemaster data.

On the surface it is a success. Most providers are making information available. (CMS, as of this past February, had sent 342 warning notices to hospitals and 124 requests for corrective action plans. It was reported that 77 hospitals rectified matters and had their cases closed.)[30] However, those providers are submitting a vast array of different price points for the same things. So, while they may be complying, that information is categorically dissimilar and disjointed, leading to further complexity and confusion. It's so varied that trying to compare apples-to-apples among all hospitals' (supposedly) shoppable services is an exercise in futility. This is the transparency paradox.

For those trying to take real advantage of this newly published pricing data there would have to be a curated, searchable database made available that could normalize information across all chargemasters, therefore turning it into meaningful and actionable analytics—a software solution that AMS will soon unveil. Only with that type of transparency and clarity can both payers and providers benefit.

The rising specialty drug cost trend that steep launch prices generate is reflected in a downloadable file of the 29 high-dollar pharmaceuticals added to PredictRx in 2021, accessible by a link towards the end of this report. The ACP among all these newly FDA-approved medications (of which yearly costs could be calculated) averaged out to be just over $530,000 per year. And since only six were of an acute/finite duration, for the vast majority those astronomical costs will recur perpetually.

Existing drugs with no competitors, and especially ones with orphan[c] designations for rare conditions, have had major price increases. **Overall, the average annual cost for orphan drugs is 25 times more expensive than traditional drugs.** The average annual cost for newly FDA-approved orphan drugs added to PredictRx in 2021 ($707,532) compared with non-orphans ($266,428) is over 2.5 times more expensive, based on ACP.

While orphan drugs certainly contribute to the problem of soaring costs so, too, does increased drug utilization and expanded indications—perhaps even more so. All of these create headaches for payers.

Unfortunately, things don't get any better for them when it comes to their cost-containment strategies. It's been reported that upwards of 20% of current drug claims do not adhere to established treatment guidelines. Worse, with regard to post-payment recovery, the success rate in recapturing those dollars lost through improperly paid claims is less than 70%.

Without question, payment integrity is key to effectively paying claims correctly. However, **to manage entire health plans effectively, payers need access to payment intelligence.** Experts have estimated that up to 80% of medical bills contain errors; moreover, 13% of the total of every medical bill is erroneous. These inaccuracies, as well as issues of fraud, waste, and abuse (FWA), are the exact types of problems that FACS analyzes, identifies, and ultimately reports on.[d] It goes well beyond the traditional payment integrity "solutions" that population management companies are ill equipped to find. FACS' advanced analytics flag complex claims that have inappropriate treatments, dosage regimens, and/or specialty drug usages, while reporting on instances of egregious drug pricing. The following graph (Figure 2), based on total claims data of $27.2 billion in allowed charges from 2021, depicts the top 10 drugs involved in flagged claims that caused the most challenges for payers, be it for financial irregularities or issues regarding clinical necessity.

[c] Orphan Drugs are defined as treatments for rare diseases that affect 200,000 or fewer Americans.
[d] FACS (Financial And Clinical Surveillance) is AMS' high-cost claim technology software system that provides AI-driven insight into the costliest and most complex healthcare diagnoses and accompanying financial impact.

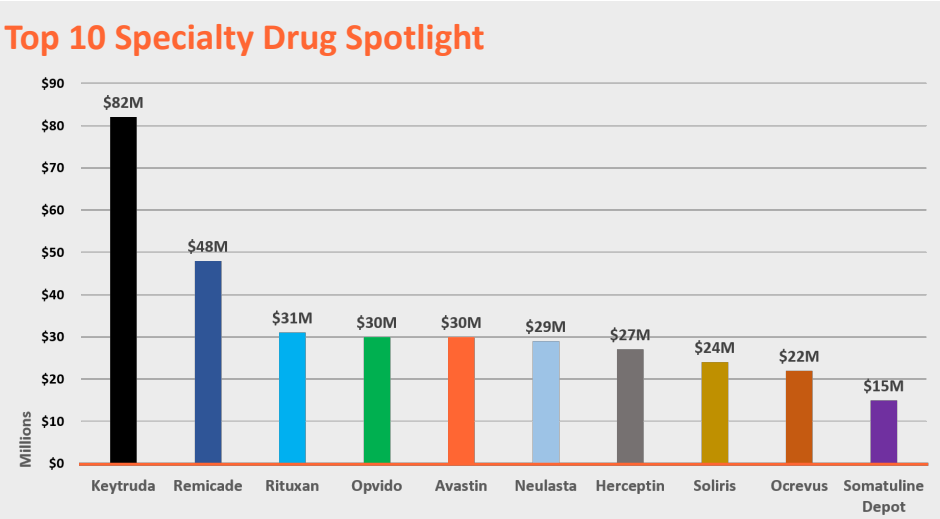

Figure 2

The chart above shows the top drugs FACS has flagged for both of those clinical or financial reasons. As we will see later in this report, the list hews closely to the top PredictRx member views. It makes sense that the drugs with complex claims anomalies resulting in an incredible sum of improvident expenditures are the very ones that AMS members are scrutinizing the most in PredictRx.

In addition to payment integrity issues pertaining to deficient claims reporting there's also the problem of drug price overspend. The screenshot below (Figure 3) shows only the drugs flagged for overcharging. So, where the former chart can best be described as "the drugs we find the most problems with in general," the latter can be considered "the drugs most commonly overbilled."

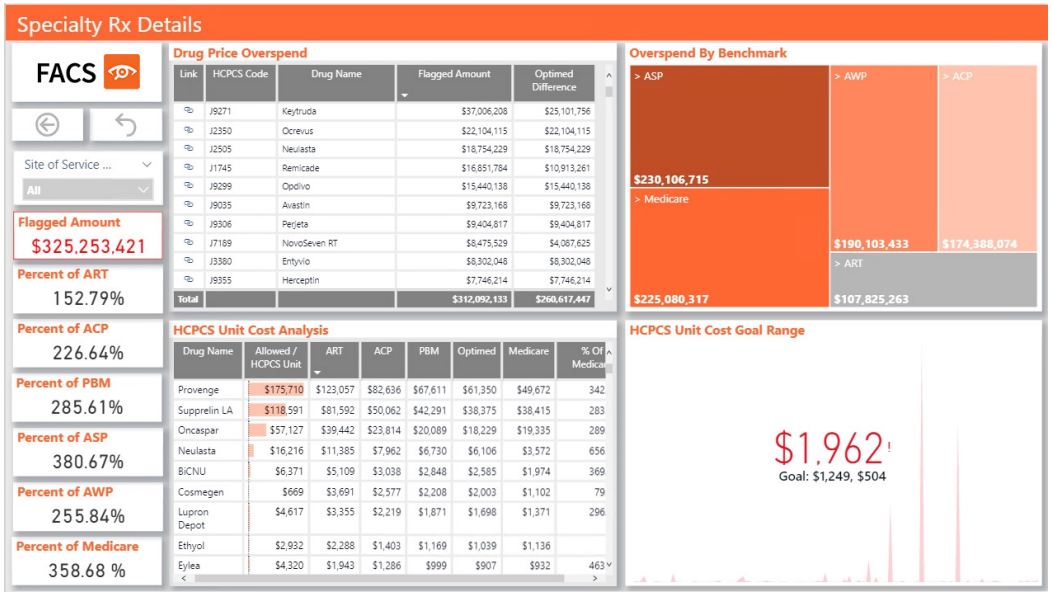

Figure 3

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Drilling down into drug overspend, this screenshot is the FACS dashboard for those $27.2 billion in allowed charges. Keytruda exceeded $37M in suspect charges. Ocrevus topped $22M. And Neulasta, Remicade, and Opdivo each had over $15M worth of questionable cost concerns for payers.

FACS shows exactly how egregious the overspend is when compared to benchmarks such as AWP and Medicare as well as AMS' proprietary ones, ACP and ART. One can plainly see that FACS flagged dollars in excess of 250% of the familiar AWP data point. The amount over ACP, a benchmark of the reasonable and expected costs of a drug, approached $175 million. ART is the absolute highest tolerable benchmark pertaining to allowed charges. Even that exceedingly high threshold was surpassed by nearly 110 million dollars in overspend. Putting it into perspective: ART is roughly 400% of Medicare and the total flagged dollars amounted to 153% of ART. This year's percentages are even worse than last year's figures. These are solvable issues.

Most cost containment companies address and fix current claims, but they do nothing to mitigate future ones. That's how they make money; it's their business model. Payers should instead look to predictive and prescriptive software tools for effective plan management. There are strategic intelligence systems that can automate, manage, monitor, and predict improper claims/payments. Payment intelligence software like FACS not only pre-empts claims but also identifies the root causes, so current and future cost problems are effectively eradicated at once. No more re-occurring claims. Yet, as we can see, payers overlook and overspend on specialty drugs year after year even though high-cost claims technologies such as PredictRx and FACS are readily available to them.

The FDA

The aforementioned Aduhelm debacle not only had 10 of the FDA advisory committee's 11 members voting against endorsement, but also caused three experts to resign, with one stating it was "probably the worst drug approval decision in recent US history."[31] The controversy prompted FDA Acting Commissioner Janet Woodcock to call for a federal review of the decision-making process that led to its approval. The investigation headed by the U.S. health department's inspector general is expected to conclude in 2023, possibly resulting in multiple reports/recommendations along the way. [32]

While on the subject of the FDA's use of advisory committees, according to recent research published in Health Affairs, during the past decade the percentage of approved drugs that the FDA had referred to advisory committees plunged from 55% (2010) to 6% (2021) annually. Entitled "Unwanted Advice?" the study article went on to state that in 10 cases the FDA moved to approve drugs while ignoring their own advisors' negative vote recommendations.[33] As the lead researcher noted, it raises "concerns about how FDA is choosing to use—or not use—independent expert advice."

More troubles were heaped upon the FDA when a JAMA Internal Medicine article came out reporting that Medicare spends millions on cancer treatments without clinical benefit.[34] That stems from the FDA's accelerated review program, which expedites their own evaluation process in order to get drugs—despite showing limited benefit or efficacy—to patients sooner. Similarly, according to an investigation written in the BMJ, **"of 253 drugs authorized through the FDA's accelerated approval pathway, 112 have not been confirmed as clinically effective."**[35]

The FDA is not unaware of the double-edged sword that is the accelerated review program. Thirty-seven of the 50 novel drug approvals of 2021 (74%) used one or more expedited programs, specifically Fast Track Designation, Breakthrough Therapy Designation, Priority Review, and/or Accelerated Approval. The Center for Drug Evaluation and Research (CDER) approved 43 of the 50 novel drugs of 2021 (86%) on the "first cycle" of review. In the preceding drug trend report, we were mindful that they seemed to have a renewed interest in scrutinizing drugs that previously went through the accelerated pathway, stating that "next year's drug report will reveal whether this trend continues." Indeed, they were. And the mere hint of that spurred more than a few pharma companies to voluntarily pull their drugs off the market and/or from current FDA consideration.[36] Still, a trend continues of fewer pre-approval pivotal trials along with a greater reliance on post-approval surrogate endpoints pertaining to novel drug approvals by the FDA in recent years. For some this is a troubling reversal on how procedures should be conducted at the FDA—a shoot first, ask questions later approach.

And in an instance of "better late than never" the FDA did some more self-regulating. Back in early 2020 they proposed pulling about 250 abbreviated new drug applications (ANDAs) after their manufacturers repeatedly failed to submit the necessary annual reports. The FDA finally followed through nearly two years later (Oct 2021), withdrawing 216 of those applications.[37]

CDER/CBER

Annual numbers of new molecular entities (NMEs) and biologics license applications (BLAs) approved by the FDA's Center for Drug Evaluation and Research (CDER) for new approvals totaled 50 novel therapeutics in 2021. Yet again orphans outnumbered traditional drugs, with 26 (52%) approved to treat rare diseases.

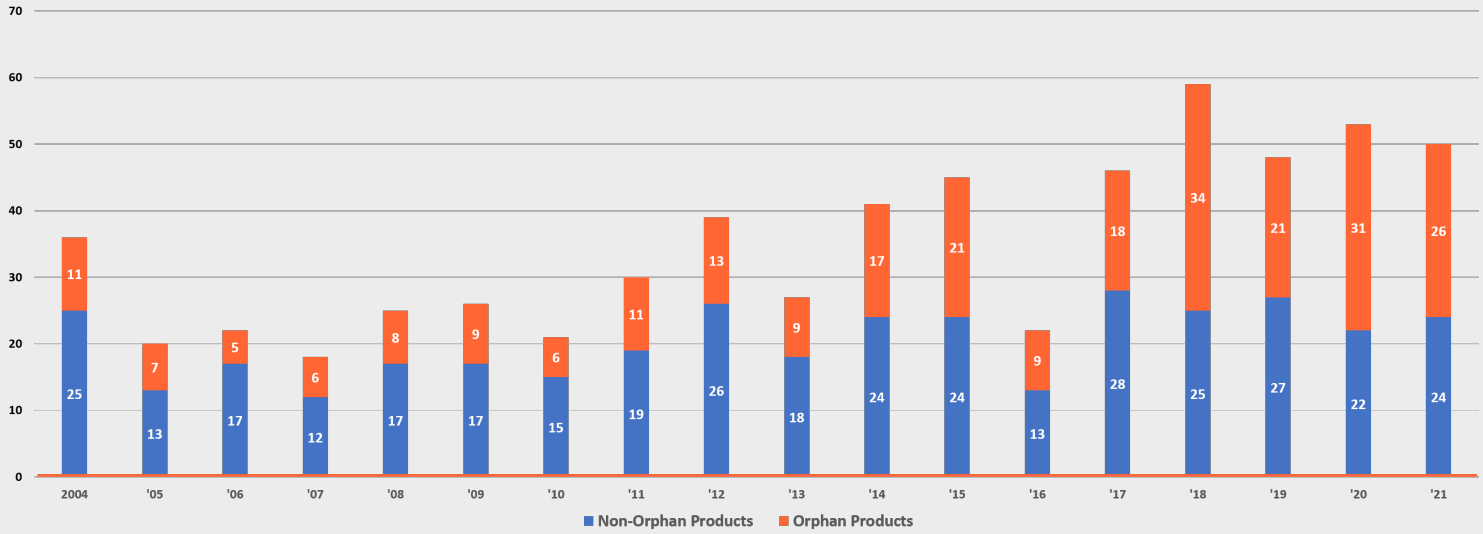

Figure 4

Approvals by the Center for Biologics Evaluation and Research (CBER) for products such as vaccines and gene therapies are not included in this drug count, which included Rethymic, the COVID-19 vaccine Comirnaty, as well as Breyanzi and Abecma, both CAR-T therapies. Cancer approvals accounted for 15 (30%) of the new approvals.

Biologics and Biosimilars

Through 2021: The FDA has approved 31 biosimilars to 11 biologics (also referred to as the reference drug). And 21 biosimilars to 8 biologics are currently available on the market. [38] AMS has found that biosimilars, on average, are about 30% lower than biologic prices.

In total, the US health care system has saved nearly $2.4 trillion in the last 10 years due to the availability of affordable generics.[39] As for the future, a recent report estimates $38.4 billion in biosimilars savings from 2021 to 2025.[40] These savings were driven by new biosimilar entries, 50% of which include the half-dozen already-approved competitors of Humira due to enter the marketplace in early 2023. An upper-bound scenario using different metrics projected savings of $124.5 billion.

Specialty Drug Costs

All the percentages and data points mentioned so far are enough to make anyone's head spin. That's because the US healthcare system has morphed into an industry designed to mystify. AMS has addressed this in an article available for download on our website which is subtitled "How Manufacturers, Insurers, Providers, PBMs, and the Government Are Keeping Us in the Dark." While AMS cannot do anything specifically to help lower the costs of specialty drugs, we can at least throw light on what the real costs are. AMS is able to do this by turning raw claims data into actionable strategic intelligence. And boy, do we have the data! Our Predict Platform is a data-driven analytics powerhouse able to pinpoint the drivers of high-cost claims. The main drivers being: Catastrophic Diagnoses, Medical-Surgical Implants & Devices, and Specialty Drugs.

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This section on specialty drug pricing is where the rubber meets the road. What do these drugs really cost? And, in turn, what are the catastrophic diseases that are impacted the most by such expensive pharmaceuticals?

Specialty drugs are continually monitored by AMS in the PredictRx drug database within the Predict Suite. This subscriber-based software system evaluates drug costs and dosing regimens. As of this writing, PredictRx is comprised of 560 specialty pharmaceuticals with an associated 2,473 drug indications—approximately 1,129 FDA-approved; another 1,344 are Notable Off-Label (NOL) uses.

It is important that these yearly costs have Adult/Pediatric, Chronic/Acute, and Non-Orphan/Orphan subdivisions. For example, pediatric pharmaceutical costs are rising because of the targeting of rare diseases that require specialty or orphan drugs. More than 50% of rare-condition patients are children. Further, **children under 2 years of age make up 9% of overall claims but a whopping 26% of million-dollar claims.**[41]

This section, as opposed to the Specialty Drug Trends segment below, focuses on the annual cost of drugs (based on 4Q2021 data in PredictRx). It's important to note the Duration column in each of the charts since a drug may be listed as Acute/Finite or Chronic/Indefinite. A drug such as Zolgensma has the staggering yearly price of $3M but it has an Acute duration; it's a one-time only infusion. There are drugs with annual costs much less than $3M; however, if they are for chronic diseases those costs will go on in perpetuity and may very well cost more than $3M for the entire treatment course (i.e., throughout the patient's lifetime). Though the following charts/grids are ostensibly Top 5 lists they are sometimes expanded to more than five where drugs are repeated.

Overall Price

Yearly Adult

This list is based on the highest ACP prices per year for Adults. Revcovi continues to top the Top 5 by a wide margin, more than double the cost of 2nd place finisher, Carbaglu. As in previous years, these are all Orphan-designated drugs with Chronic durations.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Revcovi	Severe Combined Immune Deficiency (SCID)	Enzyme Replacement Therapy	Immunostimulating Agent (other)	Yes	Adult	Chronic/Indefinite	$10,025,492	$16,676,791
Carbaglu	NAGS (N-acetylglutamate synthase) Enzyme Deficiency (Urea Cycle Disorder)	Urea Cycle Disorder and Organic Acid Disorder Agent	Metabolic Alkalosis Agent	Yes	Adult	Chronic/Indefinite	$3,969,234	$6,534,573
Feiba/Feiba NF	Routine Prophylaxis in Hemophilia A and B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Adult	Chronic/Indefinite	$3,712,800	$5,673,623
Elzonris	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	Antineoplastic Agent	Biological Response Modulator	Yes	Adult	Chronic/Indefinite	$3,121,894	$5,051,095
Exondys 51	Duchenne Muscular Dystrophy (DMD)	Neurologic Agent	Disease Modifying Agent	Yes	Adult	Chronic/Indefinite	$2,892,851	$4,576,000

Yearly Pediatric

According to Vizient, approximately 80% of known rare diseases are based on genetic mutations. It's no wonder, then, that gene therapies and CAR-T treatments are 2 of the top 3 categories of drug approvals for the pediatric population (specialty drugs being the other)—all of which pose challenges for payers concerning thorny budgetary and revenue capture issues.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Revcovi	Severe Combined Immune Deficiency (SCID)	Enzyme Replacement Therapy	Immunostimulating Agent (other)	Yes	Pediatric	Chronic/Indefinite	$4,296,639	$7,147,196
Rethymic	Congenital Athymia	Immunostimulating Agent	Human Tissue	Yes	Pediatric	Acute/Finite	$3,144,384	$6,004,900
Elzonris	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	Antineoplastic Agent	Biological Response Modulator	Yes	Pediatric	Chronic/Indefinite	$3,121,894	$5,051,095
Zolgensma	Spinal Muscular Atrophy (SMA)	Gene Therapy	Adeno-associated Virus Vector-based Gene Therapy	Yes	Pediatric	Acute/Finite	$2,950,312	$4,675,000
Demser	Management of Pheochromocytoma	Cardiovascular Agent (miscellaneous)	Catecholamine Synthesis Inhibitor	No	Pediatric	Chronic/Indefinite	$2,865,887	$5,018,255

Yearly Acute/Finite

Because most of the top drugs in the previous two charts have chronic durations, this listing only includes acute/finite durations. Notably, the top two are for pediatric populations.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Rethymic	Congenital Athymia	Immunostimulating Agent	Human Tissue	Yes	Pediatric	Acute/Finite	$3,144,384	$6,004,900
Zolgensma	Spinal Muscular Atrophy (SMA)	Gene Therapy	Adeno-associated Virus Vector-based Gene Therapy	Yes	Pediatric	Acute/Finite	$2,950,312	$4,675,000
NovoSeven RT	Treatment and Perioperative Management of Hemophilia A or B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	No	Adult	Acute/Finite	$1,814,400	$2,829,330
Acthar (AKA HP Acthar Gel)	Nephrotic Syndrome	Corticosteroid	Adrenocorticotropin Stimulating Hormone (ACTH)	No	Adult/Pediatric	Acute/Finite	$1,502,283	$2,307,892
Keytruda	Vulvar Cancer	Antineoplastic Agent	Monoclonal Antibody	No	Adult	Acute/Finite	$1,465,978	$2,256,328

Yearly Non-Orphan Adult

The most expensive drugs tend to be designated as Orphans. Of the non-orphan drugs for adults two are over $2M, while each of the remaining three are in excess of one million dollars.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Demser	Management of Pheochromocytoma	Cardiovascular Agent (miscellaneous)	Catecholamine Synthesis Inhibitor	No	Adult	Chronic/Indefinite	$2,865,887	$5,018,255
Asceniv	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Immune Globulin	Antibody	No	Adult	Chronic/Indefinite	$2,670,278	$4,944,960
Proleukin	Graft Versus Host Disease (GVHD)	Antineoplastic Agent	Biological Response Modulator	No	Adult	Chronic/Indefinite	$1,818,287	$3,472,421
NovoSeven RT	Treatment and Perioperative Management of Hemophilia A or B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	No	Adult	Acute/Finite	$1,814,400	$2,829,330
Acthar (AKA HP Acthar Gel)	Nephrotic Syndrome	Corticosteroid	Adrenocorticotropin Stimulating Hormone (ACTH)	No	Adult	Acute/Finite	$1,502,283	$2,307,892

Yearly Non-Orphan Pediatric

The top non-orphan drug for kids easily eclipses the $2M while the next two entries pass the million-dollar mark.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Demser	Management of Pheochromocytoma	Cardiovascular Agent (miscellaneous)	Catecholamine Synthesis Inhibitor	No	Pediatric	Chronic/Indefinite	$2,865,887	$5,018,255
Acthar (AKA HP Acthar Gel)	Nephrotic Syndrome	Corticosteroid	Adrenocorticotropin Stimulating Hormone (ACTH)	No	Pediatric	Acute/Finite	$1,502,283	$2,307,892
Actimmune	Primary Cutaneous Lymphomas (Mycosis Fungoides/Sezary Syndrome)	Biologic Response Modulator	Interferon	No	Pediatric	Chronic/Indefinite	$1,033,294	$1,656,658
Soliris	Glomerulonephritis	Monoclonal Antibody	Immunosuppressive Agent	No	Pediatric	Acute/Finite	$967,897	$1,500,343
Asceniv	Primary Humoral Immunodeficiency Syndromes	Immune Globulin	Antibody	No	Pediatric	Chronic/Indefinite	$623,065	$1,153,824

Drug Category

Using AMS data analytics, we can dig into drug costs that negatively affect healthcare payers at a more granular level. Below are five grids that encompass the most expensive drugs that our subscribers search most (listed as Drug Categories in the General & Coding field in each PredictRx entry).

Antineoplastics

Antineoplastic drugs are medications used to treat various cancers. While most older medications are chemically-based and are usually administered in combination with one another, newer drugs tend to be single agent targeted therapies (biologically-based). It is not uncommon for newer drugs to only be effective against specific disease mutations.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Elzonris	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	Antineoplastic Agent	Biological Response Modulator	Yes	Adult/Pediatric	Chronic/Indefinite	$3,121,894	$5,051,095
Danyelza	Neuroblastoma	Antineoplastic Agent	Monoclonal Antibody	Yes	Adult	Chronic/Indefinite	$2,036,056	$3,226,291
Proleukin	Graft Versus Host Disease (GVHD)	Antineoplastic Agent	Biological Response Modulator	No	Adult	Chronic/Indefinite	$1,818,287	$3,472,421
Keytruda	(Multiple Indications)	Antineoplastic Agent	Monoclonal Antibody	No	n/a	n/a	$1,465,978	$2,256,328
Scemblix	Chronic Myelogenous/Myeloid Leukemia (CML)	Antineoplastic Agent	BCR-ABL TKI (tyrosine kinase inhibitor)	Yes	Adult	Chronic/Indefinite	$1,449,557	$2,395,617

Monoclonal Antibodies

Monoclonal antibodies are laboratory-produced protein molecules that act as substitute antibodies. Performing through multiple mechanisms, some selectively target, attach to, and attack certain areas (antigens) while others enhance the immune system's response. These drugs generally treat cancers and autoimmune diseases. Gamifant and Ultomiris each are twice listed.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Gamifant	Hemophagocytic Lymphohistiocytosis (HLH)	Monoclonal Antibody	Immunosuppressive Agent	Yes	Adult	Acute/Finite	1,125,259	1,756,308
Soliris	(Multiple Indications)	Monoclonal Antibody	Immunosuppressive Agent	Yes	n/a	n/a	967,897	1,500,343
Ultomiris	Hemolytic Uremic Syndrome (HUS)	Monoclonal Antibody	Immunosuppressive Agent (Selective)	No	Adult	Chronic/Indefinite	580,702	899,694
Tepezza	Thyroid Eye Disease (AKA Graves' Orbitopathy)	Monoclonal Antibody	Growth Hormone Receptor Blocker	Yes	Adult	Acute/Finite	477,038	731,093
Ultomiris	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Monoclonal Antibody	Immunosuppressive Agent (Selective)	Yes	Pediatric	Acute/Finite	395,933	613,428
Gamifant	Hemophagocytic Lymphohistiocytosis (HLH)	Monoclonal Antibody	Immunosuppressive Agent	Yes	Pediatric	Acute/Finite	375,086	585,436
Adakveo	Management of Sickle Cell Disease	Monoclonal Antibody	Selectin Blocker	Yes	Adult	Chronic/Indefinite	172,450	263,120

DMARDS

Disease-modifying antirheumatic drugs (DMARDS) are immunosuppressive and immunomodulatory agents that act by altering the underlying disease rather than treating symptoms. They comprise a category of otherwise unrelated drugs defined by their use in various inflammatory conditions to slow down disease progression. Because Humira and Enbrel indications held multiple spots on the list we've expanded to make this a Top Nine.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Cuprimine	Cystinuria	DMARD (disease modifying anti-rheumatic drug)	Chelating Agent	No	Adult	Chronic/Indefinite	$945,502	$1,682,358
Kineret	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)	Biologic DMARD (disease modifying anti-rheumatic drug)	Immunosuppressant Agent	No	Adult	Chronic/Indefinite	$489,218	$781,052
Cuprimine	Systemic Sclerosis (Scleroderma)	DMARD (disease modifying anti-rheumatic drug)	Chelating Agent	No	Adult	Acute/Finite	$354,563	$630,884
Kineret	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)	Biologic DMARD (disease modifying anti-rheumatic drug)	Immunosuppressant Agent	No	Pediatric	Chronic/Indefinite	$163,263	$260,655
Humira	Crohn's Disease	Biologic DMARD (disease modifying anti-rheumatic drug)	Monoclonal Antibody	Yes	Pediatric	Chronic/Indefinite	$120,797	$196,950
Humira	Ulcerative Colitis (UC)	Biologic DMARD (disease modifying anti-rheumatic drug)	Monoclonal Antibody	Yes	Pediatric	Chronic/Indefinite	$112,879	$176,782
Enbrel	Plaque Psoriasis	Biologic DMARD (disease modifying anti-rheumatic drug)	Immunosuppressive Agent	No	Adult	Chronic/Indefinite	$111,724	$203,610
Humira	Ankylosing Spondylitis	Biologic DMARD (disease modifying anti-rheumatic drug)	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$104,816	$164,155
Simponi	Ulcerative Colitis	Biologic DMARD (disease modifying anti-rheumatic drug)	Monoclonal Antibody	No	Pediatric	Chronic/Indefinite	$100,909	$156,049

Coagulation Modifiers

This category contains miscellaneous drugs that work in different ways to prevent blood clot formation, break down clots, or produce clot formation. Highlighted here are various drugs used to treat common coagulation factor deficiencies such as Hemophilia A and Christmas Disease (Hemophilia B). As above, we've expanded to a Top 7 because of duplicate drugs in this list.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Feiba/Feiba NF	Routine Prophylaxis in Hemophilia A and B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Adult	Chronic/Indefinite	$3,712,800	$5,673,623
Coagadex	Routine Prophylaxis in Congenital Factor X Deficiency (Stuart-Prower Factor Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Adult	Chronic/Indefinite	$2,499,900	$3,804,450
Feiba/Feiba NF	Routine Prophylaxis in Hemophilia A and B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Pediatric	Chronic/Indefinite	$1,980,160	$3,025,932
NovoSeven RT	Treatment and Perioperative Management of Hemophilia A or B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	No	Adult	Acute/Finite	$1,814,400	$2,829,330
Hemlibra	Routine Prophylaxis in Hemophilia A (Congenital Factor VIII Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent (Monoclonal Antibody)	Yes	Adult	Chronic/Indefinite	$1,587,666	$2,405,277
Coagadex	Routine Prophylaxis in Congenital Factor X Deficiency (Stuart-Prower Factor Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Pediatric	Chronic/Indefinite	$1,333,280	$2,029,040
Alprolix	Routine Prophylaxis in Congenital Hemophilia B (Christmas Disease)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Adult	Chronic/Indefinite	$1,185,338	$1,905,300

Tyrosine Kinase Inhibitor

Kinase Inhibitors block various protein kinases (enzymes) that can modulate cellular function. They are commonly utilized to treat various cancers and immune conditions, such as Graft versus Host Disease. The effectiveness of these drugs on various cancers differs from patient to patient.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Ayvakit	(Multiple Indications)	Antineoplastic Agent	Tyrosine Kinase Inhibitor	Yes	n/a	n/a	$562,520	$898,503
Sprycel	Bone Cancer	Antineoplastic Agent	BCR-ABL Tyrosine Kinase Inhibitor	No	Adult	Chronic/Indefinite	$495,383	$778,102
Fotivda	Renal Cell Carcinoma (Kidney Cancer)	Antineoplastic Agent	Tyrosine Kinase Inhibitor	No	Adult	Chronic/Indefinite	$435,882	$690,690
Exkivity	Non-Small Cell Lung Cancer (NSCLC)	Antineoplastic Agent	Tyrosine Kinase Inhibitor	Yes	Adult	Chronic/Indefinite	$406,159	$669,167
Truseltiq	Cholangiocarcinoma	Antineoplastic Agent	Tyrosine Kinase Inhibitor	Yes	Adult	Chronic/Indefinite	$372,196	$614,900

Diagnosis/Disease

In addition to Drug Categories, we've also included this section of diseases that can be found within PredictDx, AMS' catastrophic diagnoses module. The following charts generally had many PredictDx member views in 2021 (shown later in this report) as well as significant drugs costs related to those diseases, which also factored into the consideration of which ones to incorporate. Because of the high prevalence of oncological diseases and their subtypes, we've split these into two subdivisions: Cancers and Non-Cancers.

Cancers

Early Stage/Locally Advanced Breast Cancer (Stages I/II/III)

Breast cancer is the most common non-skin cancer diagnosed in women. One out of every eight women will be diagnosed with this disease.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Trodelvy	Breast Cancer	Antineoplastic Agent	Trop-2 (trophoblast cell-surface antigen-2)-directed Monoclonal Antibody	No	Adult	Chronic/Indefinite	$499,829	$765,964
Avastin	Breast Cancer	Antineoplastic Agent	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$343,781	$502,833
Tukysa	Breast Cancer	Antineoplastic Agent	Tyrosine Kinase Inhibitor	Yes	Adult	Chronic/Indefinite	$329,567	$529,846
Nerlynx	Early Stage Breast Cancer	Antineoplastic Agent	Tyrosine Kinase Inhibitor	No	Adult	Acute/Finite	$292,174	$491,838
Afinitor/Afinitor Disperz	Breast Cancer	Antineoplastic Agent	Immunosuppressive Agent	No	Adult	Chronic/Indefinite	$284,136	$354,209

Advanced/Metastatic Advanced Breast Cancer (Stage IV/Recurrent Disease)

Median survival with metastatic breast cancer is 8-36 months. Five-year survival rate with metastatic disease is approximately 22%.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Demographic	Duration	ACP Yearly	ART Yearly
Trodelvy	Breast Cancer	Antineoplastic Agent	Trop-2 (trophoblast cell-surface antigen-2)-directed Monoclonal Antibody	No	Adult	Chronic/Indefinite	$499,829	$765,964
Avastin	Breast Cancer	Antineoplastic Agent	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$343,781	$502,833
Tukysa	Breast Cancer	Antineoplastic Agent	Tyrosine Kinase Inhibitor	Yes	Adult	Chronic/Indefinite	$329,567	$529,846
Piqray	Breast Cancer	Antineoplastic Agent	Tyrosine Kinase Inhibitor	No	Adult	Chronic/Indefinite	$312,986	$501,125
Nerlynx	Metastatic Breast Cancer	Antineoplastic Agent	Tyrosine Kinase Inhibitor	No	Adult	Chronic/Indefinite	$285,770	$481,058

Colon Cancer/Cancer of the Appendix

Colon cancer occurs in the large intestines. It is the fourth most common cancer in the US resulting in the third most common cause of cancer related death.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Cyramza	Colon/Rectal Cancer	Antineoplastic Agent	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$447,405	$684,080
Tafinlar	Colon/Rectal Cancer	Antineoplastic Agent	Multikinase Inhibitor	No	Adult	Chronic/Indefinite	$386,485	$617,386
Vectibix	Colon/Rectal Cancer	Antineoplastic Agent	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$386,306	$585,050
Stivarga	Colon/Rectal Cancer	Antineoplastic Agent	Multikinase Inhibitor	No	Adult	Chronic/Indefinite	$334,528	$536,168
Lonsurf	Colon/Rectal Cancer	Antineoplastic Agent	Nucleoside Metabolic Inhibitor	No	Adult	Chronic/Indefinite	$324,660	$546,749

Renal Cell Cancer/Kidney Cancer

Renal Cell Carcinoma is a type of cancer that starts in the lining of very small tubes (tubules) in the kidney. It is the most common type of kidney cancer, occurring in 85% of all cases.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Inlyta	Renal Cell (Kidney) Cancer	Antineoplastic Agent	Multikinase Inhibitor	No	Adult	Chronic/Indefinite	$552,183	$890,174
Proleukin	Renal Cell Cancer (Kidney Cancer)	Antineoplastic Agent	Biological Response Modulator	Yes	Adult	Acute/Finite	$453,223	$865,529
Fotivda	Renal Cell Carcinoma (Kidney Cancer)	Antineoplastic Agent	Tyrosine Kinase Inhibitor	No	Adult	Chronic/Indefinite	$435,882	$690,690
Cabometyx	Renal Cell Cancer (Kidney Cancer)	Antineoplastic Agent	Multikinase Inhibitor	No	Adult	Chronic/Indefinite	$353,903	$579,841
Nexavar	Renal Cell Cancer (Kidney Cancer)	Antineoplastic Agent	Multikinase Inhibitor	Yes	Adult	Chronic/Indefinite	$346,702	$555,676

Multiple Myeloma/Solitary Plasmacytoma

Multiple Myeloma is a malignant neoplasm of plasma cells that accumulate in bone marrow. Newer systemic therapy agents have extended length of time between relapses, however as of today the disease is incurable.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Kyprolis	Multiple Myeloma	Antineoplastic Agent	Proteasome Inhibitor	Yes	Adult	Chronic/Indefinite	$548,011	$821,357
Abecma	Multiple Myeloma	Antineoplastic Agent	CAR (chimeric antigen receptor) Therapy	Yes	Adult	Acute/Finite	$483,264	$922,900
Xpovio	Multiple Myeloma	Antineoplastic Agent	Nuclear Export Inhibitor	Yes	Adult	Chronic/Indefinite	$411,842	$660,031
Blenrep	Multiple Myeloma	Antineoplastic Agent (antibody-drug conjugate)	Monoclonal Antibody	Yes	Adult	Chronic/Indefinite	$395,579	$601,903
Pomalyst	Multiple Myeloma	Antineoplastic Agent (thalidomide analogue)	Immunomodulatory Agent	Yes	Adult	Chronic/Indefinite	$337,905	$545,110

Non-Small Cell Lung Cancer (NSCLC)/Early/Locally Advanced (Stages I/II/III)

NSCLC accounts for approximately 85% of all lung cancers. It is the leading cause of cancer-related death in the US, commonly afflicting tobacco smokers.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Exkivity	Non-Small Cell Lung Cancer (NSCLC)	Antineoplastic Agent	Tyrosine Kinase Inhibitor	Yes	Adult	Chronic/Indefinite	$406,159	$669,167
Cabometyx	Non-Small Cell Lung Cancer (NSCLC)	Antineoplastic Agent	Multikinase Inhibitor	No	Adult	Chronic/Indefinite	$353,903	$579,841
Rybrevant	Non-Small Cell Lung Cancer (NSCLC)	Antineoplastic Agent	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$348,895	$551,893
Retevmo	Non-Small Cell Lung Cancer (NSCLC)	Antineoplastic Agent	RET (rearrangement during transfection) Kinase Inhibitor	Yes	Adult	Chronic/Indefinite	$346,161	$551,393
Tabrecta	Non-Small Cell Lung Cancer (NSCLC)	Antineoplastic Agent	Multikinase Inhibitor	Yes	Adult	Chronic/Indefinite	$339,524	$542,370

Non-Cancers

Crohn's Disease/Ulcerative Colitis

Crohn's Disease is estimated to affect about 700,000 people in the US. Ulcerative Colitis, roughly 500,000 Americans. They are both Inflammatory Bowel Diseases (IBD).

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Stelara	Crohn's Disease	Immunosuppressive Agent	Monoclonal Antibody	No	Adult/Pediatric	Chronic/Indefinite	$185,285	$274,696
Tysabri	Crohn's Disease	Immunosuppressive Agent	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$129,795	$199,306
Zeposia	Ulcerative Colitis (UC)	Disease Modifying Agent	Immunosuppressive Agent	No	Adult	Chronic/Indefinite	$123,237	$197,714
Humira	Crohn's Disease	Biologic DMARD (disease modifying anti-rheumatic drug)	Monoclonal Antibody	Yes	Adult	Chronic/Indefinite	$120,941	$189,409
Humira	Crohn's Disease	Biologic DMARD (disease modifying anti-rheumatic drug)	Monoclonal Antibody	Yes	Pediatric	Chronic/Indefinite	$120,798	$196,950
Simponi	Ulcerative Colitis	Biologic DMARD (disease modifying anti-rheumatic drug)	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$107,756	$173,221

Rheumatoid Arthritis/Psoriatic Arthritis (RA/PSA)

Genetic factors account for 50% of the risk for developing RA. Approximately 40% of PsA patients have at least one close family member with psoriasis or psoriatic arthritis.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Acthar (AKA HP Acthar Gel)	Treatment of Rheumatic Disorders (Psoriatic Arthritis, Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Ankylosing Spondylitis)	Corticosteroid	Adrenocorticotropin Stimulating Hormone (ACTH)	No	Pediatric	Acute/Finite	$375,571	$576,047
Cuprimine	Rheumatoid Arthritis	DMARD (disease modifying anti-rheumatic drug)	Chelating Agent	No	Adult	Chronic/Indefinite	$354,563	$630,884
Tremfya	Psoriatic Arthritis	Antipsoriatic Agent (immunosuppressive)	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$114,486	$183,851
Taltz	Psoriatic Arthritis	Antipsoriatic Agent (immunosuppressive)	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$113,967	$184,012
Cosentyx	Psoriatic Arthritis	Antipsoriatic Agent (immunosuppressive)	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$105,890	$169,579

Multiple Sclerosis (MS)

Multiple Sclerosis is an autoimmune disease that affects the central nervous system. Classified into 4 subtypes, 85% of patients have the relapsing-remitting type of illness. There's no cure for multiple sclerosis.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Asceniv	Multiple Sclerosis (MS)	Immune Globulin	Antibody	No	Pediatric	Chronic/Indefinite	$340,330	$630,240
Acthar (AKA HP Acthar Gel)	Multiple Sclerosis (MS)	Corticosteroid	Adrenocorticotropin Stimulating Hormone (ACTH)	No	Adult	Acute/Finite	$321,918	$494,548
Mavenclad	Multiple Sclerosis (MS)	Disease Modifying Agent	Immunosuppressive Agent	No	Adult	Acute/Finite	$311,464	$531,265
Lemtrada	Multiple Sclerosis (MS)	Disease Modifying Agent	Monoclonal Antibody	No	Adult	Chronic/Indefinite	$174,392	$268,528
Gilenya	Multiple Sclerosis (MS)	Disease Modifying Agent	Immunosuppressive Agent	No	Adult/Pediatric	Chronic/Indefinite	$152,520	$234,054

Cystic Fibrosis

Cystic Fibrosis is a multisystem genetic disorder. Most children are diagnosed before age 2 years. Though symptoms are lifelong and there is no cure, with new therapies 80% of patients survive to adulthood.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Trikafta	Cystic Fibrosis (CF)	CFTR (Cystic Fibrosis transmembrane conductance regulator) Combination Drug	CFTR Modulator	Yes	Adult/Pediatric	Chronic/Indefinite	$433,988	$685,307
Symdeko	Cystic Fibrosis (CF)	CFTR (Cystic Fibrosis transmembrane conductance regulator) Combination Drug	CFTR Modulator	Yes	Adult/Pediatric	Chronic/Indefinite	$405,702	$640,640
Orkambi	Cystic Fibrosis (CF)	CFTR (Cystic Fibrosis transmembrane conductance regulator) Combination Drug	CFTR Modulator	Yes	Adult/Pediatric	Chronic/Indefinite	$379,417	$599,134
Kalydeco	Cystic Fibrosis (CF)	CFTR (Cystic Fibrosis transmembrane conductance regulator) Modulator	CFTR Potentiator	Yes	Adult/Pediatric	Chronic/Indefinite	$358,852	$685,307
Pulmozyme	Management of Cystic Fibrosis (CF)	Respiratory Agent (miscellaneous)	Mucolytic Agent	Yes	Adult/Pediatric	Chronic/Indefinite	$58,236	$87,052

Hemophilia A

Hemophilia A, with rare exceptions, almost always occurs in males and accounts for 80-85% of hemophilia patients. Patients are missing or have low levels of clotting factor VIII. Can be mild, moderate, or severe. Approximately 60% have severe disease.

Trade Name	Indication	Drug Category	Drug Sub Category	Orphan	Adult/Pediatric	Duration	ACP Yearly	ART Yearly
Feiba/Feiba NF	Routine Prophylaxis in Hemophilia A and B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Adult	Chronic/Indefinite	$3,712,800	$5,673,623
Feiba/Feiba NF	Routine Prophylaxis in Hemophilia A and B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Pediatric	Chronic/Indefinite	$1,980,160	$3,025,932
NovoSeven RT	Treatment and Perioperative Management of Hemophilia A or B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	No	Adult	Acute/Finite	$1,814,400	$2,829,330
Hemlibra	Routine Prophylaxis in Hemophilia A (Congenital Factor VIII Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent (Monoclonal Antibody)	Yes	Adult	Chronic/Indefinite	$1,587,666	$2,405,277
Adynovate	Routine Prophylaxis in Congenital Hemophilia A (Factor VIII Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	No	Adult	Chronic/Indefinite	$1,042,470	$1,565,460
Eloctate	Routine Prophylaxis in Congenital Hemophilia A (Factor VIII Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Yes	Adult	Chronic/Indefinite	$1,010,100	$1,614,113

Specialty Drug Trends

Specialty pharmaceuticals—which encompass orphan drugs, gene and cell therapies, CAR-T therapies, biologics, biosimilars and generics—continue their collective ascent in price and volume. The Top 25 drugs by annual drug growth (i.e., how much a particular drug/treatment escalated per annum based on 4Q2020 to 4Q2021 totals) is broken down by dollar and percentage increases.

Dollar Increase

End of year analysis reveals Feiba went up the most with a yearly ACP dollar increase above $200k from the previous year. Indications for Carbaglu, Demser, Procysbi, Elzonris, and Mepsevii all broke the $100k threshold.

Trade Name	Indication	Drug Category	Drug Sub-Category	Orphan	Demographic	Duration	2020-21 ACP $ Change
Feiba/Feiba NF	Routine Prophylaxis in Hemophilia A and B	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Y	Adult	Chronic/Indefinite	$278,460.00
Carbaglu	NAGS (N-acetylglutamate synthase) Enzyme Deficiency (Urea Cycle Disorder)	Urea Cycle Disorder and Organic Acid Disorder Agent	Metabolic Alkalosis Agent	Y	Adult	Chronic/Indefinite	$170,374.00
Demser	Management of Pheochromocytoma	Cardiovascular Agent (miscellaneous)	Catecholamine Synthesis Inhibitor	N	Adult	Chronic/Indefinite	$151,958.00
Procysbi	Nephropathic Cystinosis (Infantile Cystinosis)	Cystine-depleting Agent		Y	Adult	Chronic/Indefinite	$128,740.00
Elzonris	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	Antineoplastic Agent	Biological Response Modulator	Y	Adult	Chronic/Indefinite	$108,805.00
Mepsevii	Mucopolysaccharidosis Type VII (MPS VII; Sly Syndrome)	Enzyme	Lysosomal Glycoprotein Enzyme	Y	Adult	Chronic/Indefinite	$103,288.00
Viltepso	Duchenne Muscular Dystrophy (DMD)	Neurologic Agent	Disease Modifying Agent	Y	Adult	Chronic/Indefinite	$97,619.00
Coagadex	Routine Prophylaxis in Congenital Factor X Deficiency (Stuart-Prower Factor Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Y	Adult	Chronic/Indefinite	$89,700.00
Myalept	Treatment in Leptin Deficiency	Metabolic Agent (miscellaneous)	Hormone	Y	Adult	Chronic/Indefinite	$80,721.00
Adynovate	Routine Prophylaxis in Congenital Hemophilia A (Factor VIII Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	N	Adult	Chronic/Indefinite	$77,220.00
Ravicti	(Multiple Indications)	UCD (Urea Cycle Disorder) Agent	Nitrogen-binding Agent	Y	n/a	n/a	$74,316.00
Keytruda	(Multiple Indications)	Antineoplastic Agent	Monoclonal Antibody	N	n/a	n/a	$68,436.00
Farydak	Multiple Myeloma	Antineoplastic Agent	Histone Deacetylase (HDAC) Inhibitor	Y	Adult	Acute/Finite	$68,289.00
Rixubis	Routine Prophylaxis in Congenital Hemophilia B (Christmas Disease)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Y	Adult	Chronic/Indefinite	$66,300.00
Advate	Routine Prophylaxis in Congenital Hemophilia A (Factor VIII Deficiency)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	N	Adult	Chronic/Indefinite	$64,800.00
Gammagard S/D (Gammagard S/D less IgA)	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Immune Globulin	Antibody	N	Adult	Chronic/Indefinite	$63,898.00
Vimizim	Mucopolysaccharidosis Type IVA (MPS IVA; Morquio A Syndrome)	Enzyme	Lysosomal Glycoprotein Enzyme	Y	Adult	Chronic/Indefinite	$61,760.00
Cosmegen	Rhabdomyosarcoma	Antineoplastic Agent (antibiotic)	Cytotoxic Actinomycin	N	Adult	Acute/Finite	$60,830.00
Blincyto	Acute Lymphoblastic Leukemia (ALL)	Antineoplastic Agent	CD (cluster of differentiation) 19/CD 3-Directed Monoclonal Antibody	Y	Adult	Acute/Finite	$57,454.00
Folotyn	Peripheral T-cell Lymphoma (PTCL)	Antineoplastic Agent	Antimetabolite (pyrimidine nucleoside analog)	Y	Adult	Chronic/Indefinite	$53,718.00
Kyprolis	Multiple Myeloma	Antineoplastic Agent	Proteasome Inhibitor	Y	Adult	Chronic/Indefinite	$51,654.00
Tecartus	Mantle Cell Lymphoma	Antineoplastic Agent	CD19-Directed Autologous T cell Immunotherapy	Y	Adult	Acute/Finite	$51,095.00
Naglazyme	Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy Syndrome)	Enzyme	Lysosomal Glycoprotein Enzyme	Y	Adult	Chronic/Indefinite	$50,334.00
Padcev	Urothelial Cancer	Antineoplastic Agent (antibody-drug congugate)	Nectin-4-directed Monoclonal Antibody	N	Adult	Chronic/Indefinite	$46,635.00
Korlym	Treatment in Cushing Syndrome	Antiprogestin Agent	Cortisol Receptor Blocker	Y	Adult	Chronic/Indefinite	$45,528.00

Percentage Increase

As for which drugs rose the most on a percentage basis, Farydak led all-comers with growth greater than 25%.

Trade Name	Indication	Drug Category	Drug Sub-Category	Orphan	Demographic	Duration	2020-21 ACP % Change
Farydak	Multiple Myeloma	Antineoplastic Agent	Histone Deacetylase (HDAC) Inhibitor	Y	Adult	Acute/Finite	27.39%
Copiktra	(Multiple Indications)	Antineoplastic Agent	PI3K (phosphatidylinositol 3-kinase) Delta Inhibitor	N	n/a	n/a	19.98%
Leukeran	(Multiple Indications)	Antineoplastic Agent	Alkylating Agent	N	n/a	n/a	13.91%
Nilandron	Prostate Cancer	Antineoplastic Agent	Antiandrogen Agent (first generation)	N	Adult	Chronic/Indefinite	12.11%
Gammagard S/D (Gammagard S/D less IgA)	(Multiple Indications)	Immune Globulin	Antibody	N	n/a	n/a	10.61%
Kyprolis	(Multiple Indications)	Antineoplastic Agent	Proteasome Inhibitor	Y	n/a	n/a	10.41%
Tecartus	Mantle Cell Lymphoma	Antineoplastic Agent	CD19-Directed Autologous T cell Immunotherapy	Y	Adult	Acute/Finite	10.26%
Nplate	Immune Thrombocytopenia (ITP)	Hematopoietic Agent (platelet stimulating)	Colony Stimulating Factor	Y	Adult/Pediatric	Chronic/Indefinite	10.10%
Xofigo	Prostate Cancer	Antineoplastic Agent	Radiotherapeutic Agent	N	Adult	Acute/Finite	10.06%
Feraheme	Iron Deficiency Anemia	Iron Replacement Product	Iron Oxide	N	Adult	Acute/Finite	9.85%
Blincyto	Acute Lymphoblastic Leukemia (ALL)	Antineoplastic Agent	CD (cluster of differentiation) 19/CD 3-Directed Monoclonal Antibody	Y	Adult/Pediatric	Acute/Finite	9.79%
Otezla	(Multiple Indications)	Antipsoriatic Agent (immunosuppressive)	Targeted DMARD (disease modifying anti-rheumatic drug)	Y	n/a	n/a	9.66%
Trodelvy	Breast Cancer	Antineoplastic Agent	Trop-2 (trophoblast cell-surface antigen-2)-directed Monoclonal Antibody	N	Adult	Chronic/Indefinite	9.43%
Cosmegen	Rhabdomyosarcoma	Antineoplastic Agent (antibiotic)	Cytotoxic Actinomycin	N	Adult/Pediatric	Acute/Finite	9.26%
Odomzo	Basal Cell Carcinoma (Skin Cancer)	Antineoplastic Agent	Hedgehog Pathway Inhibitor	N	Adult	Chronic/Indefinite	9.15%
Xalkori	(Multiple Indications)	Antineoplastic Agent	Multikinase Inhibitor	N	n/a	n/a	9.00%
Nerlynx	(Multiple Indications)	Antineoplastic Agent	Tyrosine Kinase Inhibitor	N	n/a	n/a	8.96%
Xgeva	(Multiple Indications)	Bone Modifying Agent (resorption inhibitor)	Monoclonal Antibody	N	n/a	n/a	8.84%
Hyqvia	Primary Humoral Immunodeficiency Syndromes	Immune Globulin	Antibody	N	Adult	Chronic/Indefinite	8.82%
Ampyra	Treatment in Multiple Sclerosis (MS)	Disease Management Agent	Neurologic Agent	Y	Adult	Chronic/Indefinite	8.73%
Vectibix	Colon/Rectal Cancer	Antineoplastic Agent	Monoclonal Antibody	N	Adult	Chronic/Indefinite	8.71%
Arimidex	(Multiple Indications)	Antineoplastic Agent	Aromatase Inhibitor	N	n/a	n/a	8.50%
Valstar	Bladder Cancer	Antineoplastic Agent (antibiotic)	Anthracycline	Y	Adult	Acute/Finite	8.50%
Rixubis	Routine Prophylaxis in Congenital Hemophilia B (Christmas Disease)	Coagulation Modifier (miscellaneous)	Hemostatic Agent	Y	Adult/Pediatric	Chronic/Indefinite	8.42%
Trisenox	(Multiple Indications)	Antineoplastic Agent (other)	Natural Product (arsenic)	Y	n/a	n/a	8.40%

[1]Drugs that had their first/only indication FDA-approved after 12/31/18 are excluded. Similarly, diagnoses added to PredictDx after 12/31/18 are excluded as well.

Predict Suite Views

As with Drug Trends, this section includes a Top 25 for each list, providing a deep dive into the specialty drugs and diagnoses that AMS members have been researching throughout 2021. The percentage change graphs[e] are an accurate representation of drugs and diagnoses that are trending highest from one year to the next—beneficial to see where dollars are flowing.

Specialty Drugs

Not only do AMS members trust and rely on PredictRx for its benchmarked cost data, but they can also quickly access FDA approved indications, notable off-label usage, adult/pediatric dosing regimens, specialty drug coding, and critical physician commentary to verify clinical appropriateness and confidently project yearly specialty drug spend.

Views - 2021 Total

For the Top 25 researched drugs in PredictRx, Keytruda continues to reign king. Last year's #2 Rituxan and #8 Herceptin—as reflected in the percentage drops—slipped out of the top five and top 10, respectively.

Trade Name	Category	2021 Views	Percent Change
Keytruda	Antineoplastic Agent	4,016	15.07%
Stelara	Immunosuppressive Agent	3,167	23.81%
Humira	Biologic DMARD (disease modifying anti-rheumatic drug)	2,981	22.62%
Opdivo	Antineoplastic Agent	2,318	1.80%
Remicade	Biologic DMARD (disease modifying anti-rheumatic drug)	2,107	2.23%
Rituxan	Antineoplastic Agent	2,033	-15.61%
Avastin	Antineoplastic Agent	1,732	-11.27%
Ocrevus	Disease Modifying Drug	1,687	-4.80%
Revlimid	Antineoplastic Agent (miscellaneous)	1,659	28.60%
Neulasta/Neulasta OnPro	Hematopoietic Agent	1,624	3.05%
Entyvio	Immunosuppressive Agent	1,400	9.03%
Perjeta	Antineoplastic Agent	1,343	4.68%
Xgeva	Bone Modifying Agent (resorption inhibitor)	1,270	5.05%
Herceptin	Antineoplastic Agent	1,253	-25.90%
Yervoy	Antineoplastic Agent	1,214	6.30%
Trikafta	CFTR (Cystic Fibrosis transmembrane conductance regulator)	1,194	39.81%
Soliris	Monoclonal Antibody	1,178	-0.51%
Tecentriq	Antineoplastic Agent	1,002	17.33%
Lupron Depot	Antineoplastic Agent	974	4.28%
Privigen	Immune Globulin	958	34.36%
Skyrizi	Antipsoriatic Agent	949	82.85%
Prolia	Bone Modifying Agent (resorption inhibitor)	927	21.97%
Enbrel	Biologic DMARD (disease modifying anti-rheumatic drug)	907	16.73%
Carboplatin	Antineoplastic Agent	891	-9.63%
Mvasi	Antineoplastic Agent	879	120.85%

[e] Drugs that had their first/only indication FDA-approved after 12/31/19 are excluded. Similarly, diagnoses added to PredictDx after 12/31/19 are excluded as well.

AMS INTELLIGENT ANALYTICS

Trend Increase by Percentage

As for which pharmaceuticals were trending higher in terms of percentage, this list looks entirely different than the one above—only Mvasi and Skyrizi featured on both. Notably, both Mvasi and Ogivri were in the top three last year, so they continue to accumulate an interest in member views.

Trade Name	Category	2021 Views	Percent Change
Vyndamax/Vyndaqel	Cardiovascular Agent (other)	156	766.67%
Givlaari	Metabolic Agent (miscellaneous)	120	605.88%
Ruxience	Antineoplastic Agent	420	371.91%
Oxervate	Ophthalmic Agent (Miscellaneous)	153	255.81%
Ziextenzo	Hematopoietic Agent	175	250.00%
Trazimera	Antineoplastic Agent	217	219.12%
Brukinsa	Antineoplastic Agent	37	184.62%
Ogivri	Antineoplastic Agent	158	154.84%
Libtayo	Antineoplastic Agent	160	153.97%
Rinvoq	Targeted DMARD (disease modifying anti-rheumatic drug)	260	152.43%
Zirabev	Antineoplastic Agent	283	148.25%
Truxima	Antineoplastic Agent	384	141.51%
Mvasi	Antineoplastic Agent	879	120.85%
Tukysa	Antineoplastic Agent	207	107.00%
Mayzent	Disease Modifying Agent	74	100.00%
Blincyto	Antineoplastic Agent	292	98.64%
Skyrizi	Antipsoriatic Agent	949	82.85%
Lenvima	Antineoplastic Agent	516	81.05%
Revcovi	Enzyme Replacement Therapy	108	80.00%
Verzenio	Antineoplastic Agent	440	78.14%
Kanjinti	Antineoplastic Agent	719	77.09%
Padcev	Antineoplastic Agent (antibody-drug congugate)	154	77.01%
Photofrin	Antineoplastic Agent	23	76.92%
Myalept	Metabolic Agent (miscellaneous)	159	72.83%
Eylea	Ophthalmic Agent	387	72.00%

Diagnoses

For every drug there's a disease that it is meant to remedy. Included below are the most researched diagnoses within PredictDx, which provides in-depth clinical information and insight as well as key financial analytics for the costliest and most complex ailments. It's worth noting that conditions/diseases such as hemophilia, cancers (bolth solid tumors and blood cancers), and immune system/autoinflammatory disorders have drug prices as a significant percentage of their healthcare costs.

Views - 2021 Total

For the Top 25 researched drugs in PredictDx, ESRD and Early Stage Breast Cancer have swapped positions in the top 2 from last year. And it's no surprise that COVID-19 shot (couldn't resist) straight to #3.

Diagnosis	2021 Views	Percent Change
Chronic Kidney Disease/Chronic Renal Failure/End-Stage Renal Disease (ESRD)	19,115	20.33%
Early Stage/Locally Advanced Breast Cancer (Stages I/II/III)	17,682	-16.63%
COVID-19/Coronavirus	14,802	63.05%
Multiple Myeloma/Solitary Plasmacytoma	11,750	35.65%
Colon Cancer/Cancer of the Appendix	11,172	11.75%
Depression/Depressive Disorders	10,399	29.12%
Coronary Artery Disease/Hypertension (CAD/HTN)	9,818	26.49%
Dilated Cardiomyopathy/Heart Failure (DCM/HF)	9,805	12.74%
Advanced/Metastatic Breast Cancer (Stage IV/Recurrent Disease)	9,753	1.22%
Crohn's Disease/Ulcerative Colitis	9,424	22.80%
Prostate Cancer	7,384	6.81%
Rheumatoid Arthritis/Psoriatic Arthritis	7,271	21.94%
Premature Infant/Baby (Premie/Preemie)	7,192	6.52%
Aggressive Non Hodgkin Lymphoma (NHL)/Diffuse Large B-cell Lymphoma (DLBCL)/Adult	6,994	43.50%
Sepsis/Septicemia/Septic Shock	6,812	27.85%
Non Small Cell Lung Cancer (NSCLC) Stage IV/Advanced/Metastatic Disease	6,773	13.77%
Non Small Cell Lung Cancer (NSCLC)/Early/Locally Advanced (Stages I/II/III)	6,043	11.25%
Multiple Sclerosis (MS)	5,898	17.33%
Liver Diseases and Cirrhosis	5,829	24.84%
Acute Respiratory Distress Syndrome (ARDS)/Respiratory Failure	5,717	0.11%
Cerebrovascular Accident (CVA)/Stroke/Moyamoya Disease	5,364	21.38%
Osteomyelitis	5,082	53.95%
Acute Myelogenous/Myeloid/Leukemia (AML)	5,060	3.14%
Melanoma	4,701	9.55%
Rectal Cancer	4,607	11.12%

Trend Increase by Percentage

Diseases that affect children continue to top this list. At the risk of sounding like a broken record we'll say it again: children under two-years of age comprise about 6% of total stop-loss claims while making up over 25% of claims over $1M.

Diagnosis	2021 Views	Percent Change
Encephalocele/Anencephaly	109	122.45%
Biliary Atresia	282	97.20%
Gastroschisis/Omphalocele (Exomphalos)	394	84.11%
Personality Disorders	482	71.53%
Anorexia Nervosa/Bulimia Nervosa/Binge Eating	2,707	70.14%
COVID-19/Coronavirus	14,802	63.05%
Tracheoesophageal Fistula/Esophageal Atresia	444	62.04%
Pemphigus/Pemphigoid	178	61.82%
Kaposi Sarcoma	170	60.38%
Chronic Pyelonephritis/Vesicoureteral Reflux	999	58.57%
Merkel Cell Carcinoma	434	57.82%
Osteomyelitis	5,082	53.95%
Urethral Cancer	266	52.87%
Hepatorenal Syndrome	644	49.77%
Morbid Obesity	1,073	48.61%
Giant Cell Arteritis/Polymyalgia Rheumatica	428	48.61%
Meckel/Meckel's Diverticulum	286	47.42%
Bronchopulmonary Dysplasia (BPD)	824	47.14%
Anal Cancer	812	46.31%
Multiple Endocrine Neoplasia Type 2 (MEN Type 2)	145	45.00%
Scleroderma/Progressive Systemic Sclerosis	459	44.79%
Congenital Diaphragmatic Hernia	403	44.44%
Retinoblastoma	157	44.04%
Abdominal/Thoracic Aortic Aneurysm (AAA/TA)	2,252	43.71%
Aggressive Non Hodgkin Lymphoma (NHL)/Diffuse Large B-cell Lymphoma (DLBCL)/Adult	6,994	43.50%

2021 PredictRx Listing

- 29 specialty drugs added to PredictRx[f]
  - 20 Orphan Drugs
  - 1 Biologic (Rethymic)
  - 2 CAR-T Therapy (Abecma, Breyanzi)
- $530,000: Average Yearly ACP (as of their respective launch dates)
- Only 9 were of Acute/Finite duration
- 28 additional FDA-approved indications were incorporated into drugs already in PredictRx

In 2021, 29 newly FDA-approved specialty drugs were added to PredictRx. The average yearly ACP of these pharmaceuticals was $530,000.00 (as of their respective launch dates). Amondys 45, for the Treatment of Duchenne Muscular Dystrophy (DMD), topped $2.2M for the adult indication and $1.1M for pediatric (PED) indications. Scemblix, for the Treatment of Chronic Myelogenous/Myeloid Leukemia (CML), has an annual (adult) ACP of $1.25M. Rethymic, for the Treatment of Congenital Athymia (a PED-only indication), is a whopping 3.1M; unlike the other two, Rethymic is a one-time (acute) surgical implant. Of the 33 total indications (adult and pediatric) only nine are acute indications, meaning all the rest are medications used in perpetuity.

For the four new PED indications that have yearly costs the average price is roughly $1.2M, which is over 2x the overall ACP amount. So, though the sheer number of new drugs approved for pediatrics still lags those for adults, payers must remain ever vigilant regarding rising costs for that age demographic.

To view all 29 high dollar pharmaceuticals (listed in chronological order of when approved) that have been added to PredictRx in 2021 just click the link below. Also included in the download are 28 additional approvals. These are new indications for drugs already FDA-approved and listed in PredictRx.

Note that ACP and Yearly ACP amounts are as of the date the drug was entered into PredictRx. Drug indications that have n/a in the ACP column (or are highlighted in yellow) had not launched by year's end. If there is n/a in the Yearly ACP column only that means those costs cannot be accurately calculated or projected.

Download the 29 high-dollar pharmaceuticals added to PredictRx.

Transparency and clarity are essential for payers within the health and casualty industries to make informed, proactive business decisions concerning specialty drugs, particularly when it comes to pricing, dosing, and treatment analytics. That's why 90% of stop-loss carriers and hundreds of healthcare payers rely on PredictRx as the gold-standard industry resource. But PredictRx is not the only weapon in AMS' arsenal of payment intelligence software. Other technologies available to pinpoint the drivers of high-cost claims and allow payers and risk entities to effectively manage their plan and project risk are listed below.

[f] Technically, there would have been 33 total adds in 2021; however, 4 did not launch that same year.

Payment Intelligence & Clinical Integrity Resource Guide

PREDICT Rx

The premier clinical & cost resource for specialty drugs, PredictRx guides clinical appropriateness and reimbursement rates relative to the marketplace. Visit PredictRx.

PREDICT Dx

The definitive on-demand resource for delivering in-depth clinical information, empirical insight, and key financial analytics for the costliest medical diagnoses. Visit PredictDx.

PREDICT Ix

The only completely transparent implant analytics resource available, PredictIx provides accurate cost information on the actual price providers pay for surgical devices and implant-related procedures. Visit PredictIx.

FACS

Automated clinical reviews and advanced financial analytics flag and report on complex claims. FACS delivers strategic intelligence at a global level that informs and guides business initiatives. Visit FACS.

PROFILER

The industry leading platform to quickly identify current and potential high-cost members, analyze their diagnoses and specialty drug usage, and predict costs for informed medical risk mitigation. Visit Profiler.

CENSUSRATER

Closing the small group underwriting gap, CensusRater empowers brokers to quickly assess a group's total claims cost at varying specific deductibles based solely on census data. Visit CensusRater.

AI-BILL

The end-to-end I-Bill audit support solution. AI-Bill automatically identifies implant line items, seeks out supporting data from the AMS Predict Platform, and generates an easy-to-understand spreadsheet that facilitates the auditing process. Visit AI-Bill.

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