Investment Thesis Report: Prior Authorization

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FCA | VENTURE PARTNERS

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Introduction

The United States healthcare industry is the largest in the world and is growing rapidly: from 1960 to 2018, healthcare spending has gone from 5% to 18% of GDP.[1] This can be attributed to a variety of factors including increasing healthcare access and education, as well as the increasing cost and complexity of treatments on the market. According to the CDC, 53 novel drugs and 106 novel medical devices were approved in 2020 and 2018 respectively. This is compared to just 20 novel drugs in 2016.[2]

Many of these new treatments are specialty drugs, which means that while they may be useful for cell and gene therapy or be cutting edge, their price tags are higher. The FDA predicts that these trends in innovation and cost will continue, with "new cell and gene therapies, live microbial therapeutics and second-generation antibody-based products" on the rise.[3]

This trend is a double-edged sword. For patients and providers, innovation in medicine translates to higher quality healthcare and more treatment options. Yet for payors and uninsured Americans, this means rising healthcare costs. The crowded market and breakneck speed of invention also creates a pressure cooker for pharmaceutical companies to manufacture targeted, competitive drugs and devices that have superior and proven efficacy.[4]

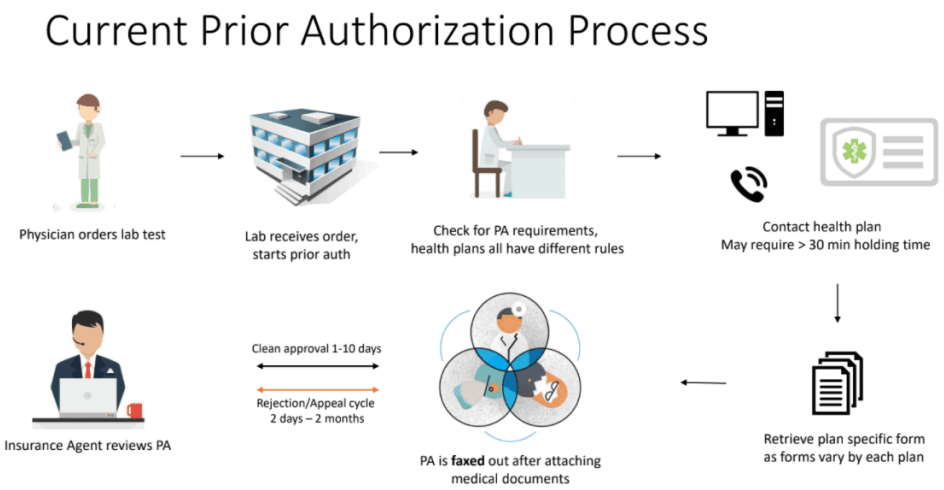
This issue led to the advent of Prior Authorization (PA). PA, also referred to as precertification or prior approval, was introduced as a protective measure for insurance companies. In theory, PA is a process by which providers gain advance approval from insurance companies before prescribing specific drugs or treatments to patients. This ensures that insurance companies have the chance to suggest more cost-effective or common drugs with strong track records before providers embark on a costly or risky treatment plan. Overall, this process allows payors to check for potentially dangerous drug interactions and cheaper alternatives, as well as to inspect the patient's demographics and medical history to determine if the fees of the service are worth coverage.[5 6]

What Typically Requires Prior Authorization?			
Cosmetic Procedures	Easily abused drugs	Drugs with Generic Alternatives	MRIs
Biologics	Psychiatric Medication Renewals	Genetic and Molecular Testing	Ultrasounds

Unfortunately for patients who require immediate or continuing care, this process can take days to complete -- up to 30 in some cases.[5] Typically, the PA pipeline begins when a medication is ordered. The provider must first figure out if a PA is needed, and then must coordinate with pharmacists and pharmacy benefit managers (PBMs) if the treatment is a pharmacy benefit drug. In particularly inefficient cases, the provider issues a 'soft PA' and then places responsibility on the pharmacist to compile patient data and determine if a PA is required, which can lead to prescriptions being left unfilled. After this alert, information about the patient is collected and submitted to the insurer by either calling, faxing, emailing,

or as of recently, over digital platforms. This information is then processed by the payor and either approved or denied.[7]

However, as of 2018, 88% of PA is partially or entirely manual.[8] Despite the fact that over 80% of healthcare practices use electronic health records (EHRs), PA has trailed behind in terms of modernization.[9] There are over 900 health insurance companies in the United States, each with a variety of plans depending on the customer. While the top five health insurance companies (Anthem, United Healthcare, Humana, HCSC, and CVS Health Corp) control 38% of the market, practitioners still have to sort through and discover each payors' policies on what treatments require prior authorization and what information is required to process a PA request. These rules fluctuate frequently and require manual

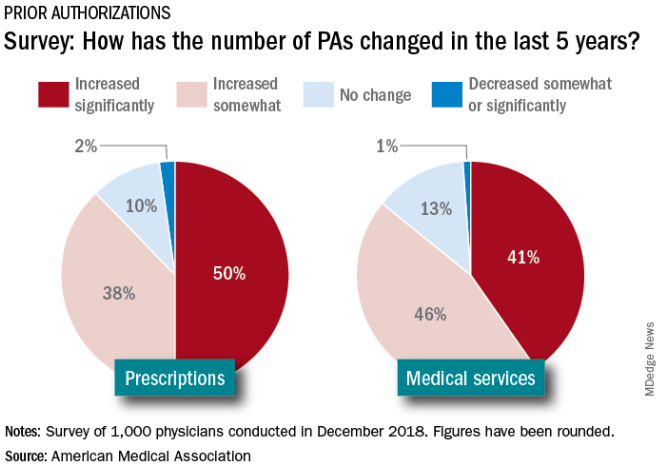


review by providers who could be spending that time on treating patients.[10] While 90% of prior authorization requests are approved, it is thought that most requests are denied simply due to incorrect information being submitted. [8]

Aside from the complexities surrounding the process as a whole, PA has been listed by physicians as the #1 cause of burnout. The volume of PAs are increasing by 20% per year due to the increasing number of medical treatments on the market. On average, practices already spend 20 hours per week dealing with PA -- time spent justifying their decisions to payors rather than dealing with patients.[11] According to physicians:

- 64% report waiting a day or more for PA approval or denial
- 91% believe that PA negatively impacts patient outcomes
- 86% report that PA burden has increased over the last 5 years

- 74% report that the process leads to patients abandoning treatment altogether[12]



Part of the frustration comes from the fact that 90% of all PAs end up being approved, yet 40% are abandoned due to the hassle and patient confusion. In the case of prescriptions, pharmacies report that 70% of patients never end up receiving the provider's original prescription.[13] This is due to the low level of digitization in the healthcare industry (7%) that makes it difficult for payors, providers, and other stakeholders to stay updated on and share pharmaceutical data, patient information, and past PA decisions. While electronic prior authorization (ePA) that pulls information from EHRs and databases has been touted as a cheaper and easier alternative to the labor-intensive PA process, as of 2019 less than 13% of all PAs are done electronically due to low healthcare digitization.[14]

Due to the complexities surrounding PA, there have been numerous attempts in the past to streamline and standardize this process. As of 2020, the Council for Affordable Quality Healthcare (CAQH), a non-profit organization in California made up of numerous PA stakeholders has released guidelines for the future of PA. The CAQH recommends that PA innovation lies in automation, transparency, streamlining and increased interoperability between stakeholders' -- payors, providers, pharmaceutical companies, pharmacies and patients -- software systems. These innovations will hopefully lead to faster response times, better continuity of care, less unfilled prescriptions, and a pivot towards value-based approvals rather than fee-for-service approvals. Yet as of 2021, current solutions do not comply with current Center for Medicare and Medicaid Services interoperability and electronic prior authorization rules. Therefore, the space for innovation is ripe.[15]

Overall, PA costs the healthcare industry anywhere from $23-31 billion dollars annually.[16] For an industry that is only 7% digitized, the market for digital healthcare is valued at over $294 billion, with a CAGR of 15.1% until 2028.[17] By 2022, the healthcare utilization market is expected to reach $6.5 billion.

By 2025, PA is expected to reach a market size of $4 billion based on averaging several confidential sources.[18] Spending on specialty treatments such as post-acute care represents over 25% of Medicare spending; this is expected to grow rapidly due to the impact of COVID as more Americans get insured. Overall, the CAQH reports that providers can save up to $355 million annually and insurance plans can save up to $99 million annually if the PA space adopts modern software and electronic data transfer methods.[15] Clearly, the demand for innovation in this space is desired by providers and payors and desperately needed by patients dependent on continuous cutting-edge care.

Due to the fragmented, outdated, and frustrating nature of the prior authorization space, there is ample room for innovation. In the next section, we'll identify the five largest innovation areas in this space and assess the current market solutions and opportunities that they present.

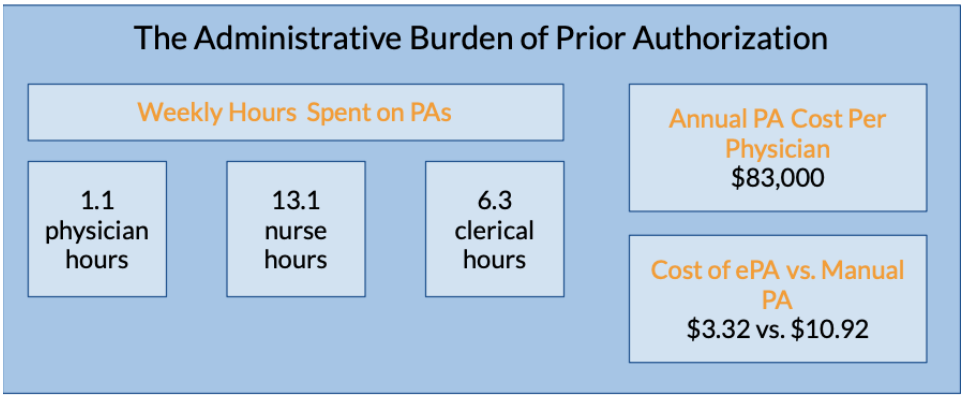
Mapping the Prior Authorization Industry

There are four key innovation areas in the prior authorization space. These spaces are automation, transparency in regard to medical innovation, streamlining patient care, and interoperability. While many of these areas have experienced rapid innovation over the past decade, there are still problems to be addressed.

Automation

As previously stated, much of the burden of prior authorization is due to the fact that it is done almost entirely manually. In fact, only 13% of prior authorizations are done electronically despite bodies such as the CAQH and the United States CMS encouraging digitization of the process.[15] The market size for automation and artificial intelligence solutions in healthcare is estimated to reach $61.57 billion by 2027 with a CAGR of 43.6%.[17]Automation is perhaps the most touted innovation when it comes to the prior authorization market and is becoming a normative idea rather than an outlier.

Automation works on both ends of the prior authorization process. For practitioners, this means that the information required for a prior authorization form will be automatically pulled from the EHR and compiled into a PA request. This process would also notify practitioners when PA is required and sift through the thousands of plan rules to fast track requests for patients who require authorization immediately. On the payor side, this means that a decision will be made automatically based on payor policies. Theoretically, artificial intelligence and machine learning can be used to learn from past payor



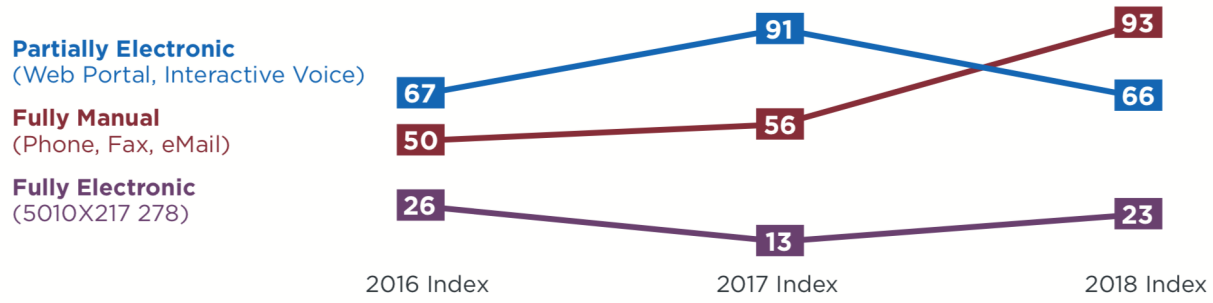
decisions and make precise decisions in mere minutes for the payor without any human error or interference.[19]

The current processes surrounding prior authorization are unwieldy and inefficient. According to physicians, 43% of first-time prior authorization requests are viewed by employees at insurance companies who have no medical experience.[20] Furthermore, 67% of physicians report that they don't know most of the time what treatments require prior authorization, which causes a further time-sink as they must peruse each patient's plan guidelines until they find an answer. Overall, physicians are "frustrated by the time, money, and resources required for prior authorizations, the frequent rejections, and the perception of being excluded from the decision-making process."[21]

Low levels of automation contribute to the deterioration of practice workflow. Revenue Cycle Management (RCM) is a huge aspect of running a practice. Due to the length of time it takes to process a prior authorization request, many patients have had to pay for expensive medical procedures by themselves, a situation called 'retrospective denial'. If the payors don't approve of the treatment, then providers have to spend more unpaid hours submitting more prior authorization requests or must cease treatment altogether if patients refuse to pay.[22]

On the payor side, a lack of automation leads to prior authorization requests being denied erroneously. 90% of prior authorization requests get approved. In fact, out of the 10% that get denied, the majority are denied due to the fact that information is missing about the patient. When patients shift health insurance, especially in the case of job transitions, the new insurer has to repeat all previous protocols that the previous insurer went through to create a digital record of what types of treatments the patient has been approved of for prior authorization. This means that payors also have to manually send off repetitive requests for patient information.[20]

Figure 1: Estimated National Volume of Prior Authorizations, Medical, by Mode, 2016-2018 CAQH Index (in millions)



Interestingly, automation in prior authorization is not a panacea. It is intended to relieve administrative burdens and to optimize workflow rather than to remove paperwork altogether from healthcare. It is important to remember that prior authorization was initially conceived as a safety protocol to prevent providers from requiring payors to fund expensive new treatments when clinically-vetted, cheaper ones already existed or if the treatment would be incompatible with a patient's previous treatment routine. Cloud-based technology and artificial intelligence can make the prior authorization process faster and smarter for all stakeholders.[23]

Current Solutions

Artificial intelligence is one of many solutions touted when discussing the automation of prior authorization. Previous solutions have included the ideas of 'gold-carding' or 'sunset programs.' Essentially, these terms mean that if a healthcare provider has a good track record of getting prior authorizations approved, then the insurance provider will issue them a 'gold-card' which would remove many of the administrative hurdles that prior authorization inherently creates. However, there are thousands of healthcare providers and healthcare plans; unless a practitioner's patients were all on the same few plans, this solution is helpful but ultimately not broad enough. Utilizing software that automates the 'gold card' process or shares a provider's track record across numerous insurance providers' plans could diminish the issues inherent within this solution.[24]

To overcome issues with practice workflow being disrupted, practitioners can hire additional administrative staff to handle prior authorization requests. This means that physicians are still able to spend time with patients and don't have to work unpaid hours filling out prior authorization requests. At the same time, this means that a small practice has to hire and pay for a new administrative assistant.

While call centers have been suggested as solutions in the past for helping to automate the prior authorization process and allow for constant payor-provider communications, these can still be time consuming and difficult to work around doctor-patient confidentiality clauses.[24]

Innovation Spotlight

There are numerous companies on the front lines of automating prior authorization. In fact, automation is a constant in most companies' plans to innovate within this space. One of the companies that has taken the lead in this space is Olive.Ai.

Olive.Ai, colloquially referred to as **Olive**, is a Cleveland, Ohio based company founded in 2012. Olive is one of the first artificial intelligences targeted at healthcare, specifically at prior authorization. Olive's algorithm focuses on improving efficiency and patient care while eliminating costly administrative errors. Aimed at hospital systems, Olive emulates manual tasks done by employees, albeit faster and more systematically than a human could. However, rather than just automating the prior authorization process across a practice, Olive has been particularly innovative due to the fact that its technology scales prior authorization workflows across an entire practice, making successive prior authorization requests more streamlined and faster. With access to over 40,000 payors, Olive can quickly retrieve prior authorization requirements from a variety of insurance companies.

As of 2021, Olive has reached a $1.5 billion valuation, backed by Tiger Global Management, Oak HC/FT and Drive Capital. This valuation comes on the heels of Olive's acquisition of PA company Verata Health for $120 million to bolster its artificial intelligence capabilities. Olive's services are employed by over 600 hospitals, including the Yale New Haven, Gundersen Health and Medstar health systems.[25] [26]

Other than Olive, **Oncology Analytics** is a trailblazer in automating prior authorization. Oncology Analytics is an Atlanta based analytics and technology company founded in 2009. Oncology Analytics is active in the prior authorization space for oncology treatments. Its platform is used to support over 5 million members in the United States and covers various therapeutics across the full spectrum of cancers. Oncology Analytics works by providing simplified and concise evidence-based analytics on cancer types and treatment options. Eliminating the need for phone calls and faxes, this company is supported by a board-certified group of oncologists. With OneUM(™), providers only have to use one portal for ePA requests, as it includes both pharmacy and provider benefits. The platform supports oral and infusion treatment types and is one of the only prior authorization companies focused on the field of oncology. Oncology Analytics' main strength when it comes to automation is its vast array of oncology

related data that it combines with claims data to ensure that patients receive the best, most cost-efficient treatment. [27]

As of 2018, Oncology Analytics has raised $28 million in its Series C fundraising. This round was led by Baird Capital Ventures. Previous investors have included Blue Cross Blue Shield and McKesson Ventures. As of 2021, Oncology Analytics serves over 5,600 providers in the United States and has partnerships with Gateway Health and Harvard Pilgrim Health Center. [28]

Another company to look at is Charlotte, North Carolina based **Digitize.ai**. The company was founded in 2017 and acquired in 2019 by Waystar for an undisclosed amount. Prior to acquisition, Digitize.ai had $700k in funding. The company was well-known for its automatic identification of treatments that required prior authorization, and rapid submission to payors. Furthermore, their technology automatically synced into a practice's EHR, making information about patients and past treatment more accessible to physicians. [29]

Digitize.ai was one of four healthcare analytics acquisitions by Waystar from 2018-2019, which is a representation of how lucrative the automation and artificial intelligence sectors of healthcare are right now. While Digitize.ai is now a part of Waystar, it was one of the first companies to utilize real-time, 24/7 analytics when it comes to prior authorization, and numerous startups and healthcare systems have since placed value on prior authorization automation that is not only simpler, but also faster to provide healthcare to their most vulnerable patients. Waystar has utilized Digitize.ai's technology to launch Hubble, an artificial intelligence used for revenue-cycle management which can learn from the billions of data points flowing through Waystar's platform. [30]

Notable Companies

Glidian

Glidian uses machine learning to streamline multiple prior authorization requests and remove faxing and phone calls from the process.

Glidian uses technology to streamline the connection between providers and payers

Glidian utilizes a real-time ePA platform that eliminates the need for faxes. The algorithm learns from previous denials to automate the process.

Raised an estimated $2-5 million. The 2019 Seed Round was led by Unpopular Ventures

www.glidian.com
Redwood City, CA

notable

Notable provides intelligent automation for healthcare, from the front desk to the back office. Notable's software has been adapted by Intermountain Healthcare and Houston Methodist Medical.

Notable works to enrich patient-physician experiences, such as the billing process, with intelligent automation

Notable works as a single central nervous system formal payments and administrative aspects of healthcare, including prior authorization

Raised $19.2 million total, $13.5 million series A led by F-Prime Capital and Oak HC/FT

http://notablehealth.com
San Mateo, California

Hindsait utilizes an AI platform to prevent unnecessary errors in healthcare. Hindsait uses natural language processing to rationalize data from faxed charts and process large healthcare datasets.

Hindsait creatively leverages data analytics to review and automate diagnostic and therapeutic prior authorizations and prevent unnecessary

Hindsait uses natural language processing (NLP) to accumulate data from EHRs and faxed charts to automate the prior authorization and benefits process

As of 2019, Hindsait has completed an accelerator. SAP.iO and GuideWell Mutual Holding have minor holdings in the company.

www.hindsait.com
Hackensack, NJ

Banjo Health has developed a prior authorization support platform for payors that utilizes artificial intelligence to drive accurate approval or denial decisions while reducing cost outcomes

Banjo uses artificial intelligence to create a decision support platform for payers.

Banjo tailors its platform to each payor's specific prior authorization criteria to reduce administrative burden.

Pre-seed round raised May 2019

www.banjohealth.com
Boston, MA

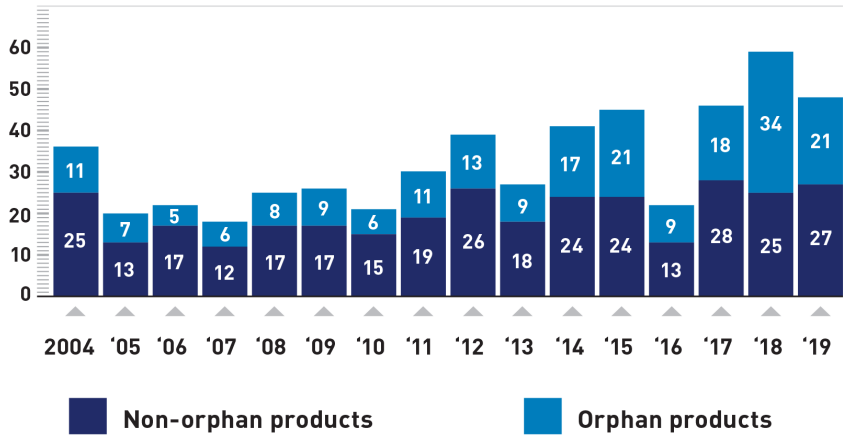
Transparency and Medical Innovation

When discussing prior authorization, automation to alleviate administrative burden is usually brought up first. However, it is important to look at this issue from a perspective other than that of the payors or providers: the pharmaceutical companies who manufacture and create the drugs that require prior authorization. There are two primary issues when it comes to keeping prior authorization on top of medical innovation: transparency and the adoption of new medical devices and treatments.

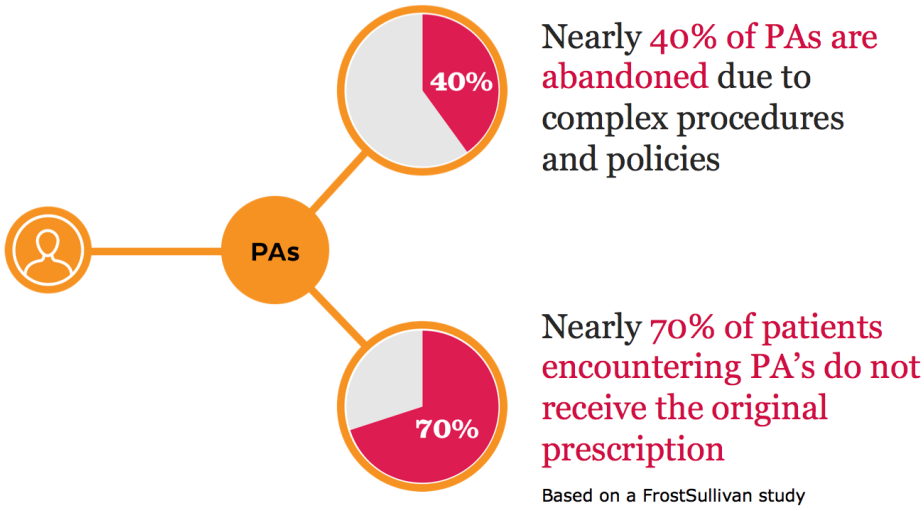
Transparency refers to software platforms that practices and payors use keeping updated on regulations and policies surrounding medical treatments. For the thousands of plans and over 900 payors in the United States, rules regarding prior auth for existing treatments change annually.[31] This small number amounts to a large amount of prior authorization policies when one considers that a single drug type could be approved for prior authorization conditionally depending on a patients' age and past health problems. These constantly shifting policies can lead to patients and providers not understanding why certain treatments are not being covered by insurance, or could lead to long manual hunts over the phone by physicians to figure out updated policies. In fact, many physicians are unaware when prior authorization is necessary: 58% of all prior authorization requests are for services that never required prior authorization in the first place.[32]

The second issue comes from the fact that the healthcare field as a whole is innovating rapidly. This is in most contexts a good thing. Cell and gene therapies are accelerating, and value-based monitoring is leading to increased market adoption of new treatments. The FDA is authorizing more drugs, devices, and treatments than ever before -- especially 'orphan' drugs that treat rare, experimental diseases and rarely turn a profit. As seen in the bar graph below, the proportion of orphan drugs approved by the FDA is increasing alongside that of 'non-orphan' products. Furthermore, the pie chart below shows the most frequent sectors that these novel drugs are being introduced into. As a whole, there has been a 15% increase in specialty drug spending annually, and specialty drugs typically require prior authorization. Therefore, the demand for software that can integrate payor databases on

prior authorization policies per treatment and per plan with new clinical information on the overflow of new treatments into the market is in high demand.[2 33]



This problem continues: pharmaceutical manufacturers are struggling more now than ever to increase the adoption of their products. Prior authorization is a key element of this. More often than not, payors will recommend that providers prescribe generic drugs with low costs and strong track records. 84% of providers say that the number of treatments that require prior authorization is increasing. As manufacturers flood the market with innovative treatment methods, they need rigorous clinical evidence of product efficacy to convince payors to approve prior authorization of their product.[34]



This has led to massive issues in prescription abandonment. According to an AMA study from 2010, only 30% of prescriptions are eventually dispensed, and patients forego drug therapy 40% of the time. Since this study is 10 years old, perhaps less than 20% of prescriptions requiring prior authorization are distributed as originally intended. This means that pharma companies are losing

massive amounts of potential sales due to administrative barriers rather than any actual failure of their products, and patients are receiving care based on evidence-based standards rather than value-based ones.[23]

Current Solutions

As previously mentioned, payors rely on clinical data to determine whether or not a drug should be approved for prior authorization. According to a 2020 American Health Insurance Policy (AHIP) survey, 98% of insurance providers rely on peer-reviewed evidence-based studies. Furthermore, 82% of these plans consult health care specialists.[35]

Pharmaceutical manufacturers need to understand that industry growth is driven by their innovative products. Pharma brands need to integrate ePA management into their customer service departments and develop methods of addressing the fact that they are losing prescriptions due to office workflow issues rather than issues with the product itself. According to management consulting firm McKinsey, big data adoption for pharmaceutical companies will allow them to accurately target niche patient populations and spot patterns in patient responses.[36] Furthermore, according to Samacare, "Bain & Company research shows that doctors who positively rate their experience of working with a drug — distinct from the "product-related attributes such as clinical data'', are ~2.5x more likely to prescribe it in the future."[37] This information assists payors in choosing what drugs to approve for prior authorization.

The responsibility for this also lies in the hands of insurance companies. Health plan Regence Health in Portland recently created a 15 month pilot with Availity, a real time health information network that is a part of Cambia Health Solutions. By combining real time health information into their network, this pilot made physicians aware of what requests for prior authorization were necessary and ended up saving 6.19 days total of provider time. This pilot also generated 'missed opportunity' reports for physicians and pharma companies to figure out where prescriptions were failing to go through.[38]

Pharmaceutical companies need to provide payors frequent clinical and real-world data on the efficacy of their products. According to Bernadette Minton, Vice President of Data Science at MCG Health, "Health systems and payers are continually looking for ways to do more with less."[39] In other words, companies that can provide hospitals and payers with data and evidence-based content to help make prior authorization easier will come out on top. For example, while MCG is not a pharmaceutical manufacturer, the company uses client data and evidence to provide payors with hospital length of stay guidelines. The current market for the pharma industry's annual spend on support services represents a

$4 billion opportunity that is expected to grow at 8% a year, and prior authorization is a large driver of this.[18]

Innovation Spotlight

Founded in 2013, Kentucky-based **eBlu Solutions** is a leader in the field of prior authorization and a part of FCA Health Innovations II fund. eBlu Solutions is a single portal solution for prior authorization, benefits verification, and financial assistance tracking. eBlu Solutions provides the most up to date information about infusion-based specialty medications to the provider. eBlu helps not just providers and payors, but also pharmaceutical companies by offering sponsored and branded workflows, partner integration, and treatment adherence monitoring to provide pharmaceutical companies with advanced data on the performance of their products. eBlu delivers first class analytics and services that increase pharma revenue opportunities and are scalable across growing organizations.[40]

eBlu Solutions as of 2021 has raised a $11.4 million Series A round led by OCA Ventures, FCA Venture Partners, and Mutual Capital Partners. Over the COVID-19 pandemic, eBlu saw its revenue double. eBlu has partnered with pharmaceutical companies, HUBs, and IMCs across the country.[41]

Samacare is another company innovating in this space. Founded in 2018, this San Francisco, CA based company works with manufacturers to ensure that patients receive the most effective drugs in the least amount of time. Samacare has raised $5.8 million in funding since its inception. Samacare utilizes a cloud-based software to track, submit, and manage prior authorizations across a variety of payor plans and practices. HUB Education services are also provided by Samacare, which ensures that market access teams no longer face the 'monkey-in-the-middle' dilemma of trying to help providers navigate the murky waters of new medical inventions and regulations. Samacare provides data to pharma market outreach teams to provide, "instant visibility into the obstacles practices and patients face in accessing physician-administered drugs, and leverage to help them address those issues before they spiral."[42]

Pria is an innovator in this space as well. Pria is based in Connecticut and was founded in 2012 with the mission of providing patients access to insurance coverage of the most innovative medical devices and treatments. Pria performs prior authorizations along with benefits verification, but stands out due to its emphasis on getting insurance coverage for treatments on the cutting edge of innovation.

These capabilities drive market adoption of treatments that would have been passed over by insurance companies for less effective generic drugs and devices.[43]

Case Study: CoverMyMeds

Notably, **CoverMyMeds** was an early innovator in the prior authorization space. CoverMyMeds was founded in 2008 in Ohio by Sam Rajan and Matt Scantland. Essentially, CoverMyMeds operates by seamlessly integrating into pharmacy EHRs. The company was one of the first to provide software to healthcare providers that aimed to eliminate the hassle of paperwork from the medical process so that patients can receive the medication that best fits their lifestyle and insurance plan. The company mission was inspired by the incredible amount of prescription abandonments that the co-founders saw at pharmacies. This inspired them to create the first all-payer, all-medication PA platform that connects payors, healthcare providers, and pharmacies. To this date, CoverMyMeds has helped over 180 million patients, and was recognized in 2020 by Frost and Sullivan as the winner of its North American Product Leadership Award.[44]

Just three years after its founding, CoverMyMeds had raised $1 million from funds such as JumpStart Ventures. By 2014, CoverMyMeds had opened a second office in Columbus, OH and grown from 2 to 150 employees. That same year, Francisco Partners made an investment in CoverMyMeds so that they could continue growth across the payor, provider, manufacturer, and pharmaceutical spaces. This led to CoverMyMeds $1.3 billion acquisition by McKesson, a global healthcare company that CoverMyMeds was partnering with since 2010 through McKesson's RelayHealth Pharmacy.[45] It is estimated that as of today, CoverMyMeds' software suite "automates the medication prior authorization process for more than 500 electronic health records (EHR) systems, 49,000 pharmacies, 700,000 providers and most health plans and PBMs."[46]

Relevant Companies

Agadia's PAHub helps streamline the prior authorization process across all channels, services, and lines of business.

Agadia provides a certified web-based solution expedite the delivery of critical health care services

PAHub is used by over 40 leading health plans and works to increase ePA adoption for specialty medicine under patients' medical benefits.

Agadia's funding is confidential, but their PAHub platform is used by the nation's largest health plans and PBMs, covering over 70 million lives

www.agadia.com
Parsippany, NJ

CoverMyMeds, part of McKesson, reduces prescription abandonment by providing a free prior auth solution for providers that partner with health plans and pharmaceutical manufacturers.

CoverMyMeds integrates with 75% of EHRs to provide an ePA solution to practices

CoverMyMeds aims to increase medication access with its tech-enabled hub services and streamlined workflows.

Raised $5.1 million since 2011

www.covermymeds.com
Columbus, OH

i[ic] Informatics In Context
Bridging the Digital Divide

Informatics in Context is a cloud based pioneer. IIC's authorization engine is real time, fully automated and is self-editing when treatment outlines are edited by payers.

Informatics in Context (IIC) uses clinical integration of healthcare databases to extract relevant clinical information about healthcare

IIC works with device companies as well as healthcare facilities to extract and synthesize clinical information

Raised $2.1 million total

www.informaticsincontext.com
Boston, MA

InteliSys Health™

InteliSys provides insurers and patients with frequently updated, transparent data on prescription drug prices. Their system can be embedded into an EHR.

InteliSys Health is the nation's first real-time prescription transparency program

InteliSys is not strictly prior-authorization related, but it facilitates multi-stakeholder conversations on prescription drug prices and value.

Raised $5.2 million over 2 rounds since 2015

www.inteliscript.com
Las Vegas, NV

Streamlining Patient Care

A large debate in the insurance space is that of value-based care versus fee-for-service-based care. At the end of the day, while prior authorization may be an administrative issue, healthcare itself is about the patients. Therefore, prior authorization and its subsequent approval is dependent on whether payors and providers subscribe to evidence-based care, value-based care, or some combination of the two.[47]

Most medical providers agree that prior authorization is detrimental to patients. According to an AMA study, 90% of physicians agree that prior authorization has negative effects on patients; 16% believe that it leads to emergency room visits.[12] Furthermore, prior authorization is frequently required for MRIs and for emergency room procedures, which essentially puts providers in the difficult position of charging patients before they know if insurance will cover a procedure. Since prior authorizations can take up to 15 days, if a patient requires emergency surgery or an immediate treatment plan alteration, healthcare could remain out of reach for those who cannot afford the cost out of pocket.[22]

Furthermore, prior authorization in the past has disrupted continuity of care for patients. For cancer patients, who require frequent scans and tests, approval can be delayed up to a month, which is a critical time a provider could be using to make a diagnosis or even start a patient on a chemotherapy regimen. For many labs that deal with oncology specialists, it is normative to perform tests prior to a prior authorization getting approved -- knowing that they may not be paid -- due to the danger and speed of cancers. This is especially prominent for psychiatrists, many who struggle to get medication renewals for schizophrenic patients who appear to be on the mend or emergency admissions to psych units.[48]

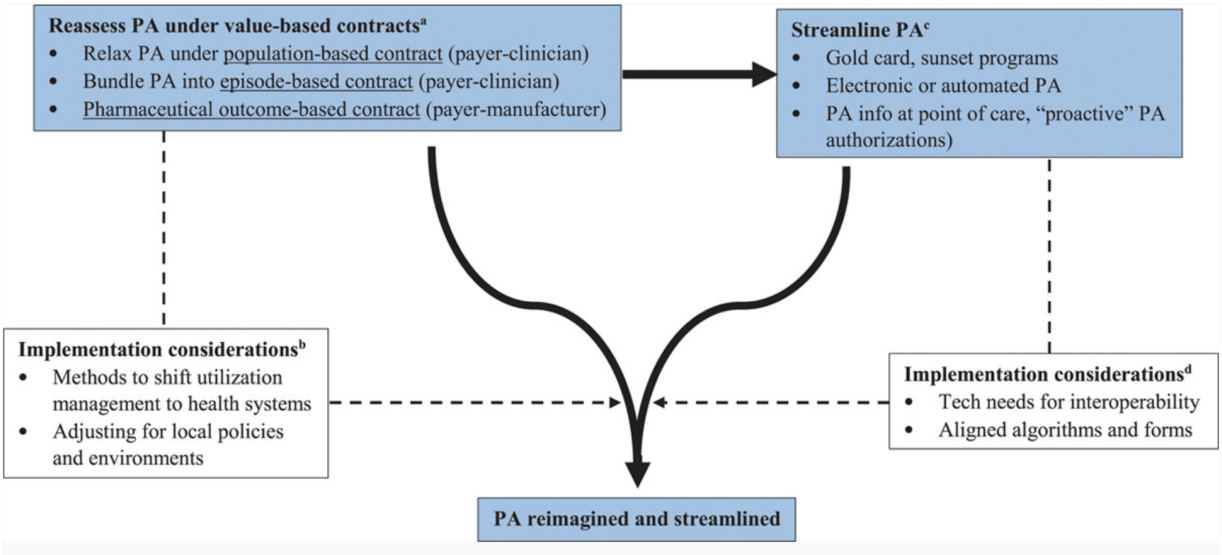
The current standard for insurance plans to use is that of evidence-based care: 98% of insurance plans use peer-reviewed evidence based clinical trials to evaluate whether or not they should approve a drug for prior authorization. This standard is unlikely to change in the field of prior authorization. However, due to the speed of innovation of medical devices and treatments, many stakeholders in this issue believe that value-based care standards will determine whether or not a drug is approved for prior authorization.[35]

Value based care essentially refers to removing administrative steps of the prior authorization process to focus on the value of the therapy to the patient rather than the cost. While this may seem counterproductive to the goals of payors to minimize costs, the financial reasoning behind this is that it will prevent medical costs down the line. Patient care has failed to streamline due to most payors and

providers not developing a network to fast track therapies that require instant approval, nor has it developed efficient enough portals to communicate this information among numerous stakeholders.[47]

Current Solutions

Organizations such as Blue Cross Blue Shield of Western New New York have initiatives that aim to eliminate prior authorization requirements altogether. In 2017, BCBS of Western New York eliminated prior authorization requirements for more than 200 protocols. 100 of these protocols were investigational ones that were typically approved after being appealed by physicians. BCBS of NY reported an 8% increase in satisfaction as well as an uptick in usage of post discharge home care prescriptions. While prior authorization cannot be fully eliminated, the idea of reviewing historical patterns of how patients have responded to treatment to determine if a request should require prior authorization is a way to increase the quality of patient care and decrease payor costs.[49]



Another strategy that has been used to streamline patient care is to focus on user experience (UX). Companies at the forefront of prior authorization such as CovermyMeds use screen shot and click testing, task based usability testing, and card sorting methods to map how their users think and constantly innovate their platforms to be simpler and easier to use. At the same time, this type of thinking must be extended to patients as well -- the CMS has recently put patients over profit by giving them access to current and pending ePAs, "which should result in fewer repeated requests for prior authorizations, reducing costs and onerous administrative burden to our frontline providers."[50]

Innovation Spotlight

Founded in 2011, Bethesda, MD based **Caremetx** specializes in optimizing patient experiences. Aside from their prior authorization services, Caremetx offers patient services from intake to outcome. Caremetx was on the front lines of turning prior authorization-related call centers into digital 'HUBs' where multiple stakeholders can communicate and share information; offering transparency to the prior authorization and benefits management process. Caremetx offers "real-time access to decision-making data and confidence-building insight." The company's software works as a HUB management platform and connects the patient with data from payors, providers, and manufacturers. Caremetx's two services, *Connect* and *Innovation* provide interoperability between multiple HUBs and real time business intelligence, respectively.

Since January 21st, 2021, Caremetx has entered a strategic growth partnership with General Atlantic and the Vistria Group. As of 2020, Caremetx has launched its own independent reinsurance product for rare disease specialty and cell and gene therapies. In recent years, Caremetx has branched out from HUB services to its goal of reducing access and affordability challenges. As it branches out with significant investment from Vistria and General Atlantic, Caremetx continues to serve over 80 companies.[51]

Midwest based **CenterX** was founded in 2009 with a goal of streamlining ePA and prescription benefit services. The company was initially founded to provide physicians with patient-specific benefit information for e-prescriptions. CenterX also has developed a fully digital ePA platform that can be integrated seamlessly with any EHR system. The platform digitizes any prior authorization step that has to be done over fax, meaning that physicians never have to leave the EHR while making an authorization request. CenterX has combined its eprescription capabilities with user friendly ePA capabilities to provide patients with rapid, cost effective care. In fact, CenterX's platform ensures adherence and continuity to a prescribed course of treatment.[52]

Finally, **Itiliti** was founded in Minnesota in 2019 to eliminate wasteful administrative steps during prior authorization processing. Itiliti operates on a platform of medical policy optimization. Rather than just being open to payors and providers, Itiliti provides patients with real time information on whether their procedures are covered or if they will be authorized. This software easily integrates with Availity and EHRs like Epic to reduce the amount of prior authorization submissions in the first place by immediately letting providers know if a time-consuming prior authorization is necessary or not.[53]

According to MedCityNews, Itiliti has two main products: PA Checkpoint and PA Complete. The former determines if prior authorization is needed or not, and the latter, due to come out later in 2021, uses artificial intelligence to determine if patients meet the criteria for prior authorization in the first place.[54]

Relevant Companies

Siris Medical focuses on improving radiation oncology outcomes by connecting its database to providers and payers to uniquely tailor treatment to patients.

Siris Medical uses InsightRT PA and Clinical Decision Support (CDS) to connect providers with the treatment that's best for the patient.

Siris Medical automatically personalizes patient prior authorization pathways to provide transparency.

As of 2020, raised $2.3 million in Series A round led by Wisconn Valley Ventures. Has raised $8.3 million total

www.siris-medical.com
Burlingame, CA

Clinicalbox provides precision prior authorization seamlessly integrated with EHRs, especially for surgeons. Clinicalbox creates structure patient communications and educational messages.

Clinicalbox digitizes medical policy documents to intelligently approach prior authorizations

ClinicalBox is unique for its stream of patient communications and financial transparency solutions

Raised $1.7 million

www.clinicalbox.com
Cambridge, MA

OODA Health enables collaborative, real-time interactions between stakeholders and puts the responsibility on payers for patient collections

OODA utilizes patient-risk models to manage care. OODA reimagines the patient billing experience via a mobile payment structure.

OODA puts payment responsibilities on insurance companies, ensuring that patients are quickly aware of treatment cost, pulling them into the PA process.

Raised $42.5 million in Series A round led by Oak HC/FT and Threshold.

www.ooda-health.com
San Francisco, CA

Interoperability

While automation is important, one of the largest issues facing prior authorization today is the slow uptake of technology and lack of interoperability between various stakeholders in the process. Essentially, it is difficult for payors and providers to make decisions when patient information and relevant data are dispersed across incompatible EHRs and data systems. While Epic is the EHR used by 45% physicians, it only covers about half of patients in the United States. HUB platforms and prior authorization software companies face the challenge of integrating a variety of EHRs with an existing plethora of plans, patients and manufacturers.[55]

Digital healthcare investment is expected to be a lucrative market in the future; as of 2018, it was worth $7 billion. Yet despite this, a 2018 Family Medicine survey found that ⅔ of a patient's visit is taken up by a physician accessing or using the EHR. No matter how 'online' healthcare goes, the administrative backbone of healthcare is here to stay and EHR usage has remained remarkably unchanged since its widespread adoption in 2005.[56]

As previously touched on, pharmacies are often shut out of the prior authorization process. Pharmacy staff's careers typically are geared less towards patient engagement and more towards developing a deep understanding of medications and medication use. In fact, payor's top 5 criteria for deciding on whether to approve a certain medication all fall well within a pharmacist's specialty. Pharmacies typically can push a prior authorization form to a prescriber directly, but only 25% of these notifications result in said authorization getting submitted to a plan. Due to the aforementioned issues with transparency, the pharmacy may never know what happened to their authorization request. However, over the past 5 years, pharmacists and lab workers have found themselves increasingly in a care-related role. 78% predict that they will have a greater role in patient care by 2027. The figure below lists the five most common treatment questions patients come to pharmacists about over their prescribers.[57]

Labs also find themselves shut out of the prior authorization process. Labs typically have a business relationship with the providers rather than a relationship with patients. This means that when

prior authorizations go wrong and they're unsure of whether or not to run a test or charge for a test, they must use go-betweens to communicate with the practitioners, and they can only push so hard before they start to lose business.[6]

This problem can be attributed to the fact that there is little standardization in the field of prior authorization. To begin, pharmacy and medical drugs typically have entirely different benefit systems and thus prior authorization becomes more complicated when a provider has to access different portals or communicate through a pharmacy to collect information; this becomes even more difficult when pharmacies are left out of the prior authorization process.[58]

This problem can also be attributed due to the fact that the United States has been slow to issue standardization requirements for payors. As of January 2021, the Centers for Medicare and Medicaid services passed the "CMS interoperability and Prior Authorization" rule that encourages payors, providers, and patients to provide transparent access to pending and current prior authorization requests. This rule requires payors such as "Medicaid and CHIP managed care plans, state Medicaid and CHIP fee-for-service programs (FFS) and issuers of individual market Qualified Health Plans (QHPs) on the Federally-facilitated exchanges (FFEs)" to use application programming interfaces (APIs) to provide physicians with data. Essentially, this means that data will be more convenient and accessible over a variety of electronic devices. This rule has pushed the majority of payors to look for software solutions that can provide this as well as provide speedy prior authorizations in line with the Fast Healthcare Interoperability Resources (FHIR) standard. These rules will also apply between payors if patients switch plans.[59] [60]

Interoperability nowadays has also come to refer to the ideal of seamless interfacing between different EHR and payor electronic systems rather than just seamless communication between individual stakeholders. As of 2019, 64% of healthcare providers want ePA directly integrated into their EHR. Many EHR software solutions such as Epic have these capabilities, but this is not a standard option due to most regulations and standards being directed towards payors to standardize health plans.[13]

Current Solutions

A common solution for interoperability has been for states to create guidelines for payors and providers within their borders. As previously mentioned, CMS has put in new rules regarding data sharing between payors. However, these rules do not apply to all insurance plans, nor do they actually require complete interoperability beyond provider-payor interactions. Interoperability is also typically

regulated at the state level rather than the federal level, which means that plans face different regulations depending on where their patients live. [60]

Another common solution has been to create a one-step prior authorization platform or go through a HUB. Traditionally, prior authorization takes multiple laborious, non-digital steps. A way to ensure a less expensive solution to interoperability is for databases and software services to provide real time updates to treatment and patient information databases so that prior authorization decisions can be made and communicated to all parties automatically. [13]

Overall, the largest issue with interoperability is the slow digitization of healthcare. Healthcare spending is expected to reach $5.7 trillion by 2026, yet as of 2021, 90% of the healthcare industry still relies on fax machines, and 39% of physicians exclusively use pagers and landlines to communicate. In other words, healthcare's administrative infrastructure is not adequately modernizing to keep up with the financial growth of the industry.[61]

Innovation Spotlight

Surescripts is perhaps the most relevant company that has innovated in this space. Founded in 2003 in Arlington, Virginia, Surescripts provides assistance for providers looking to conduct e-prescriptions and for those looking to transition to ePAs. Surescripts is the leading provider of e-prescriptions in the United States, with 94% of pharmacies as of 2019 using its software. Surescripts' ePA technology automatically integrates with EHR and pharmacy software and has a large backdrop of first class clinical health information. Surescripts partners with payors, providers, pharmacies and pharmaceutical companies to manage patient data to minimize the cost and time it takes for prior authorizations to be approved. The company is owned by CVS Health and Express Scripts (owned by Cigna), and touts connections to virtually all EHR vendors in the United States. [62]

Myndshft is another company innovating in this space. Myndshft was founded in Arizona in 2016 with the goal of making modern digitization technologies -- artificial intelligence, blockchain, big data, and analytics -- accessible to stakeholders in the healthcare revenue cycle process. Myndshft's technologies target the post-acute and alternative care site markets. Working with the 'fragmented, portal based and legacy point solutions' that target single stakeholders, Myndshft aims to simplify the manual workarounds that stakeholders have to take to overcome the gaps in healthcare technology. Myndshft also complies with the 2021 CMS interoperability and Electronic Prior Authorization rules, which means it is an easy option for stakeholders looking to rapidly become up to date on standards and

regulations. Myndshft offers two products: Myndview and Myndauth. The first provides a real time medical benefits check and a fully automated submission of the prior authorization request at the point of care. The latter provides real time previews and adjudication in the provider's EMR. Their goal is to complete this process in 3-5 seconds using blockchain records and smart contracts. [63]

Infinx, founded in 2012 in San Jose, California, is an innovator in the prior authorization space. Its targets are radiology, cardiology, orthopedics, laboratories, pharmacies, and physical therapy practices. Infinx's cloud-based platform helps practices digitize their revenue cycle and is compliant with the 2021 CMS rules about API usage. Infinx also provides a single portal for seamless experience. Prior Authorization specialists are outsourced in Infinx's model for complicated requests so that providers can spend more time with patients. [64]

Relevant Companies

eviCore healthcare

eviCore healthcare is a medical benefits management company that is working to digitize and streamline revenue cycle and benefits management processes

eviCore's intelliPath is a prior authorization solution that is connective, real time, and integrated with major EHR vendors.

intelliPath is a single portal platform that seamlessly fit into workflows and speeds the communication of critical information.

Acquired in 2017 for $3.6 billion by Express Scripts Holding.

www.evicore.com
Bluffton, SC

Azalea Health is a leading provider of integrated Telehealth and cloud-based electronic health records. Azalea provides mobile patient portals and emphasizes care coordinate innovation.

Azalea Health leverages its large network of providers to cater to patients via telehealth, easy to access portals, and prior authorization services.

Azalea is notable for its rural health outreach, and provides prior authorization services for ambulatory clinics, hospitals and physician offices.

Raised $12.31 million to date. Furthermore, in 2021, the company participated in a private equity round led by LLR Partners.

www.AzaleaHealth.com
Atlanta, GA

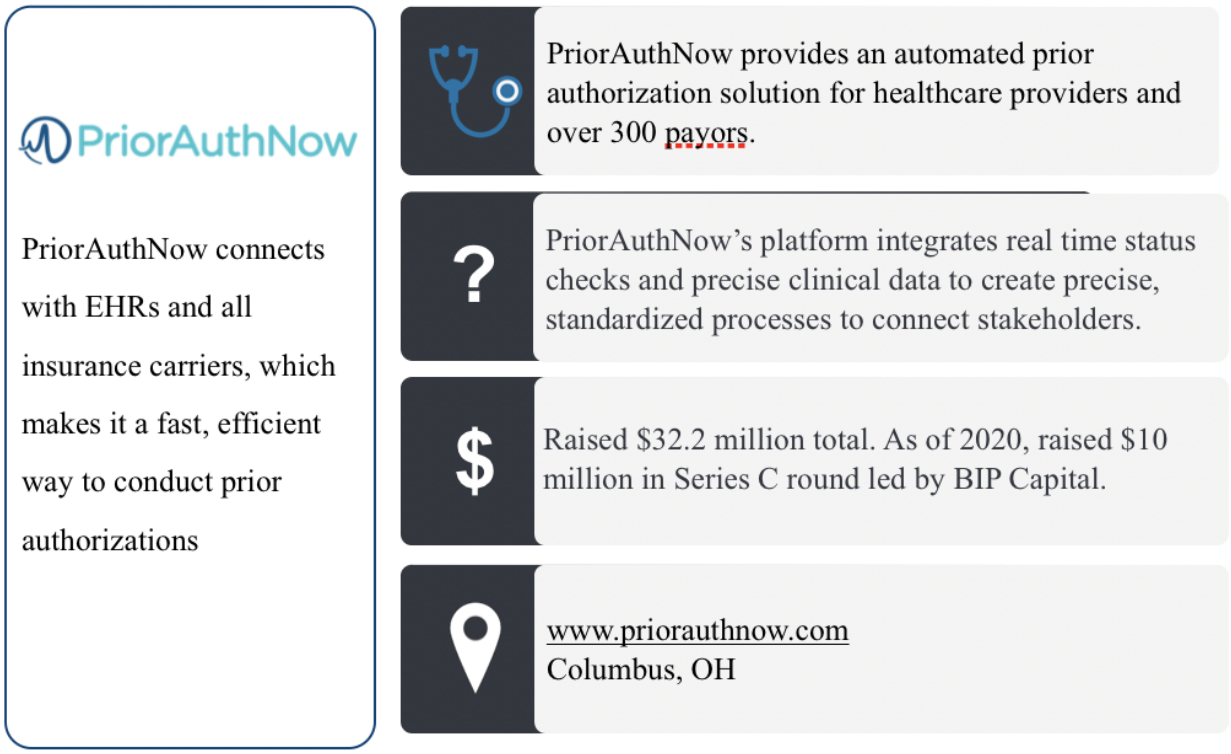
Cohere integrates with fee-for-service and value-based systems and is designed to increase interoperability in healthcare.

Cohere utilizes machine learning to break down the unintentional silos that have made prior authorization more complex

Cohere Health's Cohere*Next* platform supports and auto-approves treatment plans as the shift to value based care requires more interoperability

As of April 2021, raised $36 million in Series B round led by Polaris Partners, Flare Capital Partners and Define Ventures. Has raised $56 million total.

www.coherehealth.com
Boston, MA



Barriers to Innovation

The possibilities that innovating prior authorization suggests are exciting. However, there are multiple barriers to innovation that should be considered.

Firstly, the electronic nature of automation and artificial intelligence presents the issue of data theft. Innovations in automation and innovation mean two things: information about a patient is being automatically filled into a prior authorization form, and said information is being accrued from a variety of payor and provider databases. According to the NCBI, the internet of medical things (IOMT) now contains countless sensitive patient medical files, and just one of these files can sell for hundreds of dollars on the dark web. From 2005 to 2009, over 220 million individuals were affected by healthcare data breaches. Since the Affordable Care Act of 2010 required a digitization of records and usage of EHRs, healthcare companies have seen a 72% increase in cyber-attacks. Digitizing prior authorization means that this issue will likely be compounded.[65]

Secondly, there is a huge financial barrier associated with digitizing the medical field. A healthcare industry data breach alone costs over $6 million, compared to typical data breaches costing around $3 million.[65] Aside from the costs from any loss of data that healthcare systems may suffer due to digitization, making prior authorization digital is incredibly expensive. While creating the digital infrastructure is expensive, the 2021 CMS guidelines, innovative startups, and the opportunity cost associated with not digitizing may accelerate this process.

Thirdly, insurance payors are disincentivized to modernize the prior authorization space. The financial health of insurers during the 2020 COVID-19 pandemic has never been better. While providers are stuck billing unsuspecting patients for treatments that have been denied prior authorization, as well as navigating the expensive, arcane maze of prior authorization requirements, payor companies are looking to continue saving money. Therefore, the incentive between stakeholders to innovate in the industry are not the same. As of 2020, the American Health Association concluded that prior authorization for insurers has become a tool used to avoid reimbursement of patients and to restrict access to expensive treatments. According to the American Health Association (AHA), in 2019, a United States investigation found that the largest commercial insurer was systematically denying treatment for financial reasons. In other words, the insurer was ignoring the purpose of health insurance to deny coverage of medically necessary treatments solely to save money. In the same report, the AHA describes how one 17 hospital network spends $11 million annually to comply with prior authorization requirements. It is a challenge to innovate in this area when on one hand providers desperately desire a solution to high costs and burnout, and on the other insurance companies make the process more difficult by denying coverage, abusing prior authorization processes to save money, and changing healthcare plan rules halfway through contract years. Due to this barrier, potential innovators in this space should tailor their solutions to payors as well.[11]

Conclusion

Overall, the intentions between prior authorization are important: to protect payors and patients from paying too much for treatments that have generic alternatives or are not highly clinically vetted. However, with medical innovation skyrocketing and technology such as gene therapy and personalized medicine on the rise, many of the good intentions behind prior authorization have soured.

Today, prior authorization is a thorn in the side of many stakeholders in the healthcare industry. For providers, it is an administrative barrier to care and a direct challenge of their medical expertise. For

pharmacies and labs, it is an element that makes the treatment process less transparent and more expensive. For pharmaceutical companies and pharmaceutical marketing teams, it is a barrier to market entry, and for patients, it is a dangerous and time-consuming hurdle to jump to get to their important treatment.

Overall, there are four key areas where prior authorization can be innovated in. Firstly, it can be automated with the assistance of artificial intelligence, reducing the administrative barriers of its process. Secondly, prior authorization needs to be faster and keep up with medical innovation. Thirdly, prior authorization can be improved by streamlining the process and making it more transparent in the interest of providing value-based care to patients. Fourthly, prior authorization needs to be standardized and the software used in any solution should support interoperability between different EHRs and payor databases.

As of 2021, CMS has set rules encouraging stakeholders in this process to innovate and digitize. There is a considerable market to be captured, whether this is in claims denial or in healthcare information technology and software. However, at the end of the day, prior authorization innovation will lead to better patient outcomes and more fluent communication between payors and providers.

Looking at the innovation spotlights in conjunction with stakeholders' pressing desires for improvement of the prior authorizations system, it is clear that the market for PA is a multibillion dollar opportunity. PA is an important element of utilization management in the healthcare industry, and it is clear that great strides are still to be made in the areas of automation, transparency, streamlining, and standardization. FCA hopes to make additional investments in this area going forward.

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