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Breaking the Bottleneck: Streamlining Prior Authorizations and Unlocking Patient Access to Specialty Medications

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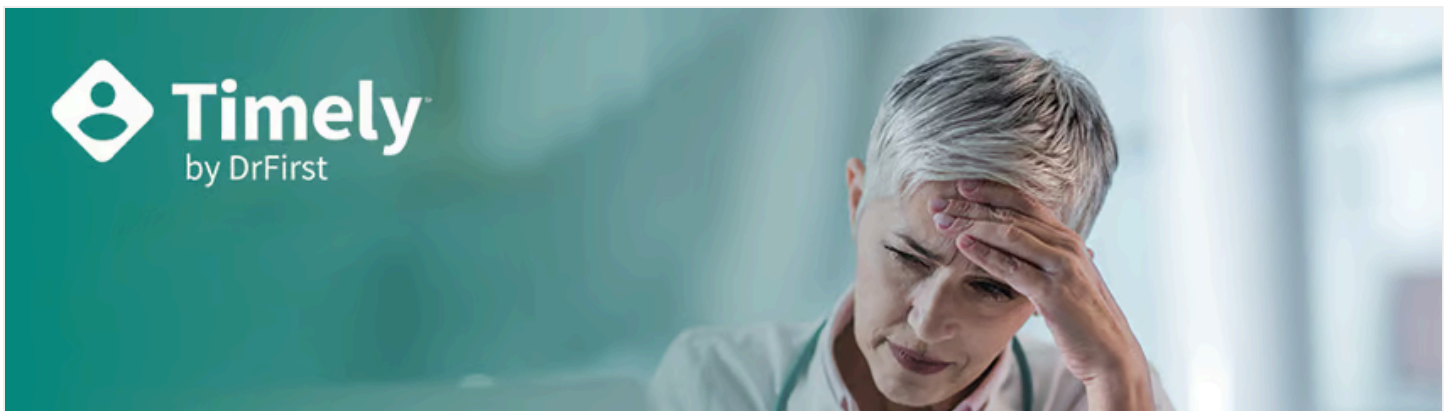

(DrFirst)

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When Marie D'Orsaneo's rheumatoid arthritis worsened, her doctor prescribed Rituxan, a pricey injectable medication. But her health plan's approval process dragged on, turning days into weeks. As she waited, her condition deteriorated, forcing her to quit her job, move in with relatives, and seek inpatient care.

Featured in an *NBC News* broadcast on the high cost of specialty medications in January 2013[1], D'Orsaneo's ordeal was far from unique. The situation for patients has gotten progressively worse in the years since. ()

With their high cost and need for special handling and administration, specialty drugs often require a prior authorization (PA). In fact, 71% of infusion therapies prescribed for rheumatologic conditions today require payer approval, according to research published in *Arthritis Care & Research.*[2]

But it's not just the costs that are climbing—so are the hoops doctors must jump through. A staggering 80% of physicians report that prior authorizations are increasing, regardless of whether the drug falls under pharmacy or medical benefits.

For healthcare providers, this process is more than just a hassle—it's a hazard. Nearly 90% of doctors surveyed by the American Medical Association (AMA) describe the administrative burden of prior authorizations as high or extremely high[4].

Prior authorization challenges abound

As if the cost and complexity of specialty medications alone weren't enough to keep patients from starting and staying on vital therapies, an uptick in the volume of PAs, the near-constant flip-flop of payer rules, and a total lack of provider insight into patient health and benefit information all conspire to make patient access worse.

The journey to get patients with rare and chronic conditions on a highly specialized therapy starts, incredibly, with a web search to determine if a particular medication is likely to require an approval.

Consider the following all-too-typical scenario: A patient presents at a provider's office with a complicated disease. The physician assesses the situation and quickly determines what treatment is needed. The provider then struggles to figure out if the patient's insurer will cover the desired treatment. A scavenger hunt of sorts ensues. One staff member rifles through the ubiquitous "payer bible," a well-worn three-ring binder filled with insurance requirements, while another tries to recall what the insurer has approved in the past. Then, the team must figure out whether the medication falls under the patient's pharmacy or medical benefit plan, as insurers have different rules for each. ()

Meanwhile, someone else is making phone calls to payers with one hand and scrolling through insurance websites with the other in a desperate search for coverage information, current policies, and updates. All of this takes considerable time and results in plenty of frustration.

According to a post published as part of the American Medical Association's *What Doctors Wish Patients Knew* series, patients might wait days, weeks or even months to receive treatment when PAs are required by insurers. As such, the AMA contends that "existing processes present significant administrative and clinical concerns."[5]

One of the most frustrating hold-ups stems from confusion over whether specialty drugs are covered under medical or pharmacy benefits. For example, infusions, in-office injections and chemotherapy are sometimes covered as medical benefits rather than pharmacy benefits. () To complicate matters even more, an estimated 49% of covered individuals have a separate benefit tier for specialty drugs.[6]

Specialty pharmacies feel the prior authorization pain, too ()

While providers face challenges in obtaining PAs, specialty pharmacies also encounter significant obstacles in ensuring that patients receive their medications promptly. These barriers, though less recognized, are equally detrimental in delaying patient access to necessary treatments.

Of particular concern is the frequent misrouting of specialty therapies to non-specialty pharmacies, which often cannot fill these prescriptions. According to a study by DrFirst, specialty pharmacies are 30% more likely to successfully fill a rheumatological medication than non-specialty pharmacies. However, over a quarter of high-cost specialty medications are mistakenly sent to non-specialty pharmacies, leaving patients in limbo and delaying critical, even lifesaving treatment.

For the physicians who prescribe these complex therapies, not having access to real-time benefit and pricing information, copay savings, and financial assistance in workflow can severely limit their ability to provide optimal patient care. Despite industry efforts to empower patients and providers with real-time price transparency through new regulations, challenges remain. For example, the ONC's HTI-2 proposed rule includes a mandate for health IT systems to include functionalities for immediate access to pricing information, but not until 2027 at the earliest.

Even when EHRs offer price transparency, the information is often limited. A provider may identify a specialty biologic drug as the ideal treatment but may not know whether the patient's insurance will cover it, if approval is required, or if there are any available copay savings or other pricing options.

When this critical information is available at the point of care, providers and patients can collaboratively explore alternative treatments if insurance coverage is unlikely. Discussing price and affordability as part of the care visit helps prevent prescription abandonment due to sticker shock at the pharmacy. In fact, 83% () of consumers in a DrFirst survey reported that discussing price with their doctor helped them find an affordable therapy option.

Perhaps most concerning, hub services, which are designed to simplify the process by acting as intermediaries between patients, providers, and pharmacies, are often underutilized. These services provide education and guidance to ensure easy medication onboarding and adherence. However, many patients are either unaware of hub services or do not fully engage with these resources.

These barriers lead to a variety of risks for patients, including:

- **Care delays:** 94% of physicians report prior authorization contributes to care delays 'sometimes,' 'often' or 'always.'
- **Care disruptions:** 89% of physicians report that prior authorization interferes with continuity of care.
- **Adverse outcomes:** 33% report that prior authorization has led to a serious adverse event for a patient in their care.[7]

Perfecting an imperfect process

To overcome medication access challenges, electronic prior authorization needs to seamlessly exist within a healthcare organization's existing workflow. An electronic solution should streamline the entire process by offering real-time medical benefits and automating the PA process from end to end.

In addition, it's important for providers to adopt a platform that leverages AI, machine learning and robotic process automation to streamline complex benefits pricing and processes for *both* pharmacy and medical benefits. A platform that readily engages patients and offers unified medication management can also help facilitate access to needed therapies.

As Colin Banas, chief medical officer at DrFirst, explains: Providers can reduce manual effort by more than 70% and cut claims rework by 90% when using a system that automatically prescreens PA errors and provides a dashboard for monitoring the status of requests.

"Leveraging a platform with all these components is a significant step toward easing prior authorization burdens for providers and pharmacies, and the benefits extend to payers and pharma, as well. Most of all, though, it's a giant leap forward for all those patients who previously suffered as their health deteriorated and their lives were put on hold because they were not able to access the treatment their doctor determined was right for them when they needed it most," said Banas, M.D., M.H.A.

Timely by DrFirst *is a personalized mobile communication experience that works to improve medication adherence in partnership with life science brands. Timely is built on the strength of e-prescribing pioneer DrFirst's EHR integration and complemented by streamlined access to specialty medications covered under medical benefits. Timely extends the reach of prescribers to support the patient journey where and when it matters most – at the point of inception – when patients are making the decision to start treatment. To learn more about how Timely can improve adherence and engagement for your organization, please contact: 888-271-9898 |* *www.timely-health.com* (http://www.timely-health.com/) | *info@timely-health.com* (//mailto:info@timely-health.com)

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The editorial staff had no role in this post's creation.

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After FDA rejection, Sanofi and Regeneron show data that could pave way for Dupixent to treat hives condition

By **Kevin Dunleavy**
Sep 11, 2024 01:00am

Dupixent | Regeneron Pharmaceuticals | Sanofi | chronic spontaneous urticaria

New data from a phase 3 trial could pave the way for Sanofi and Regeneron's Dupixent to score an FDA approval to treat chronic spontaneous urticaria. The U.S. regulator rejected the companies' previous bid for a nod in October of last year. (Sanofi)

Eleven months after sustaining a rejection (https://www.fiercepharma.com/pharma/sanofi-and-regenerons-dupixent-suffers-rare-setback-crl-treat-hives) from the FDA for Dupixent to treat chronic spontaneous urticaria (CSU), Sanofi and Regeneron have presented data from a phase 3 trial that could help push the megablockbuster across the finish line in the indication.

The LIBERTY-CUPID C study met its primary and secondary endpoints in testing patients with Dupixent who were already receiving background antihistamine therapy. It is the third phase 3 trial for Dupixent in CSU, a severe inflammatory condition that causes hives and deep swelling on or under the skin.

In the trial of 151 children and adults, those who took Dupixent plus standard-of-care (SOC) antihistamines experienced an average 8.6-point reduction in itch severity (on a scale of 21) compared to a 6.1-point reduction for patients who received SOC plus placebo.

The Dupixent group also experienced a 15.9-point reduction in itch and hive severity (on a 42-point scale) versus an 11.2-point reduction for the control group.

The measurements were taken after 24 weeks on therapy.

Additionally, 30% of Dupixent-treated patients reported a complete response compared to 18% of those on placebo.

“The positive pivotal data from this study reinforce the potential of Dupixent to offer a new treatment option for the many people suffering from chronic spontaneous urticaria who do not respond to standard-of-care antihistamines,” Sanofi’s chief medical officer Dietmar Berger, M.D., Ph.D., said in a release.

The companies will share the data with the FDA in the hopes of bringing Dupixent to CSU patients “as soon as possible," Berger added. The partners plan to file their regulatory resubmission before the end of the year. Earlier this year, Dupixent was approved for CSU in Japan.

The trial confirms results from the successful LIBERTY-CUPID A study, which tested Dupixent plus SOC antihistamines against antihistamines alone in patients with moderate-to-severe CSU.

In the LIBERTY-CUPID B trial, however, Dupixent came up short, failing to significantly reduce symptoms of people who did not have success with the lone treatment approved in for CSU—Novartis and Roche's Xolair. While the trial was stopped for futility, the companies noted that Dupixent provided numerical improvements in the each of the main evaluation criteria, including itching.

The result helped convince the FDA to reject Sanofi and Regeneron's application for approval and ask (https://www.sanofi.com/en/media-room/press-releases/2023/2023-10-20-21-00-00-2764252) the companies in a complete response letter for more efficacy data.

More than 300,000 people in the U.S. suffer from CSU that is inadequately controlled by antihistamines, the companies said.

Dupixent has been on the market for seven years and has been approved in atopic dermatitis, asthma, rhinosinusitis, eosinophilic esophagitis and prurigo nodularis. Another indication may soon be coming as the FDA is reviewing Dupixent as a treatment for chronic obstructive pulmonary disease.

If approved in CSU, Dupixent would become the first new treatment in the indication in more than a decade, according to Sanofi and Regeneron.

In 2023, Dupixent's sales increased by 33% to $11.6 billion. More than 1 million patients have been treated with the monoclonal antibody, the companies said.

Xolair, which was approved for CSU in 2014 and covers most of the same indications as Dupixent, generated sales of $4 billion last year.

With Xolair soon to face biosimilar competition, Novartis is working to bring a new CSU treatment to the market as it recently presented data from two successful phase 3 trials for oral BTK inhibitor remibrutinib. The company expects to submit for approval of remibrutinib next year.

Pharma | Xolair | Novartis | Roche

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After BIOSECURE Act passes in House, targeted Chinese companies say they're 'deeply' concerned

By **Fraiser Kansteiner**
Sep 10, 2024 10:40am

BIOSECURE Act | House of Representatives | Senate | China

The BIOSECURE Act gained wide bipartisan support on the House floor, though nearly all lawmakers who voted against it were Democrats. (Getty Images)

After much anticipation and concern, the BIOSECURE Act—which would prevent U.S. companies from working with certain Chinese biotech service providers—has passed a key threshold.

Late Monday, the U.S. House of Representatives voted 306-81 in favor of the bill, which was introduced in January and seeks to halt federal contracts with five named Chinese life-sci companies—WuXi AppTec, WuXi Biologics, BGI Group, MGI and Complete Genomics—over alleged national security concerns.

The bill gained wide bipartisan support on the House floor, though nearly all lawmakers who voted against it were Democrats, BioSpace reports (https://www.biospace.com/policy/biosecure-act-sails-through-house-passage-lines-up-senate-vote).

With the bill having passed through the House, it will now be up to the Senate to decide on the fate of the BIOSECURE Act.

Still, the most likely route for the bill to become law would involve tucking (https://www.statnews.com/2024/09/09/house-passes-biosecure-act-targeting-china-biotechs/) BIOSECURE into a larger legislative vehicle, such as the annual defense bill or government funding legislation, according to Stat.

The companies named in the bill have been quick to defend themselves in recent months. Naturally, they're none too pleased with the latest development in Congress.

"WuXi AppTec is disappointed in the House's vote on the proposed BIOSECURE Act, which pre-emptively and unjustifiably designates our company without due process," WuXi AppTec said in an emailed statement.

"We and many across the pharmaceutical and life sciences industry are deeply concerned about the legislation's impact on U.S. leadership in biotechnology innovation, drug development, and patient care, as well as the implications for the costs of care and life-saving and other vital medications," the research giant added.

Complete Genomics, for its part, said it was "deeply disappointed but not entirely surprised" that geopolitics, rather than facts, drove the House passage of the BIOSECURE Act. In turn, the Senate will have to spend the final months of the session working to fix "this broken and flawed bill," the genomics company continued.

Despite support for the BIOSECURE Act in Washington, industry watchers have raised concerns about the complicated work that would be required for U.S. and European drugmakers to untangle themselves from their Chinese contractor partners. The current version of the bill would require drugmakers to sever ties with the named Chinese contractors by 2032 to retain their positions on Medicare and Medicaid, which serve as crucial sales drivers for many pharmaceutical companies.

Among those who opposed the bill, Rep. Jim McGovern, D-Massachusetts, ranking member on the House Rules committee, was quick to make his concerns known. Over the weekend, he told (https://www.reuters.com/markets/us/democrat-vote-against-bill-restricting-chinas-wuxi-biologics-bgi-2024-09-07/) Reuters that the process for including named companies in the legislation was inconsistent and that he could not get a clear explanation about WuXi Biologics' inclusion.

In a post on X Monday night, McGovern admitted (https://x.com/RepMcGovern/status/1833272050053460399) he has "very serious concerns" about China's efforts to exploit the U.S. biopharma industry, steal sensitive information and endanger national security. Nevertheless, he branded the BIOSECURE Act a "weak bill" that could "actually make the problem even worse."

McGovern voted "no" on the bill Monday night and urged his colleagues to do the same.

Despite uncertainty over the future of the bill, a certain degree of reputational damage has already been done, as evinced by a recent L.E.K. Consulting survey. The group recently found (https://www.fiercepharma.com/pharma/biosecure-act-hurts-life-sciences-companies-confidence-chinese-partners-survey) that the bill had dramatically undermined U.S.-based life science companies' confidence in working with Chinese firms.

U.S. companies were most concerned about working with Chinese CDMOs, followed by contract research organizations and drug development partners, according to L.E.K.'s poll.

Manufacturing | Pharma | United States | WuXi AppTec | WuXi Biologics | Complete Genomics