by Carolyn Gretton

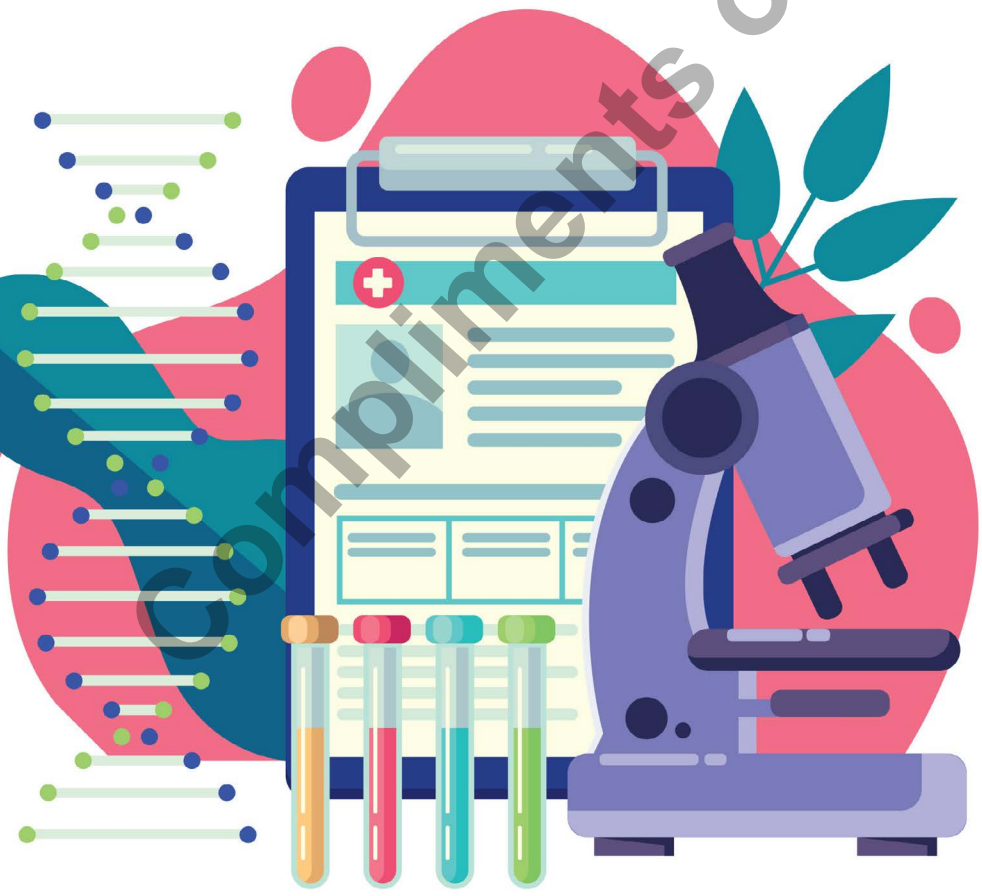
PATIENT ACCESS: Keeping the Channel Open During a Crisis

A managed access program enables pharmaceutical and biotechnology companies to make certain investigational or unapproved treatments available to eligible patients through their prescribing physicians. But what happens when the supply chain is disrupted by a pandemic, such as COVID-19?

The worldwide spread of COVID-19 has upended many aspects of the life-sciences industry. Researchers, manufacturers, and providers are now focused on finding medicines to treat the sickest patients, as well as developing a vaccine against the SARS-CoV-2 strain of the coronavirus.

Most pharma and biotech companies say they have not yet seen any interruptions in their supply chain due to COVID-19. However on the R&D side, a number of companies have temporarily paused recruitment for all new and ongoing clinical studies in most countries, except where required to develop and test vaccines and antiviral medicines to combat the virus.

On its website, Pfizer notes that this policy does not affect patients already enrolled in clinical trials, but the company has not commented on whether managed access programs will be impacted. Investigators have initiated an independent Phase II study of Pfizer's oral Janus Kinase (JAK) inhibitor tofacitinib in patients with SARS-CoV-2 interstitial pneumonia, but the company cautions the drug is not approved for this use and should not be given to patients with an active serious infection.



Merck has also temporarily suspended enrollment in ongoing studies and halted the start of new clinical trials due to COVID-19 while making sure that patients already participating in existing studies are able to continue their treatment and receive appropriate care and monitoring.

Novartis is collaborating with Incyte to study Jakavi in treating cytokine storm, a severe immune reaction that can lead to life-threatening respiratory complications in patients with COVID-19. As part of the process, Novartis has set up an international compassionate use program for eligible patients, subject to local regulations. Novartis and Incyte are also working to make sure there's enough supply of Jakavi to ensure access for existing patients while managing the anticipated increase in COVID-19-related requests.

"We are seeing a significant shift toward clinical trials and expanding access to potentially promising therapies for COVID-19 as well, potentially delaying the development or introduction of new programs for other diseases," says Natalie Douglas, co-founder of RareiTi.

Raymond Johnson, senior VP, management supervisor, at Ogilvy Health, observes that manufacturers are bracing for a shift in prescription volume away from new patient starts driven by COVID-19 and its subsequent restrictions on interpersonal contact. "As a result, patient-support programs are trending toward providing innovative approaches

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REAGAN TULLY
RxCrossroads by McKesson

that empower patients and improve their experiences in order to improve adherence to therapy," he says.

Ms. Douglas says the effects of the crisis are numerous for patients already in trials or early access programs. "Access to therapy and medical staff during self-isolation can be a challenge, especially if they have to go to hospital or a clinic," she says, noting that the risk of contracting the virus for those with a serious underlying condition could be critical, and that in some cases patients have chosen to come off therapy.

"RareiTi Care is designed around the patient and their needs, most of which can be fulfilled at home and through virtual support, so for many patients already familiar with this kind of support, the current crisis will present the same challenges they are already familiar with and we are all now facing with social distancing and home schooling," Ms. Douglas adds. "Our recommendation to the biopharmaceutical industry at this time is to think about addressing some of these issues now. They may be surprised how quickly an access program can be up and running, even in this crisis environment. There are many people who still need access to healthcare systems, drugs, and services during this time who could be assisted."

Reagan Tully, VP, office of customer focus and delivery, RxCrossroads by McKesson, says her organization is keenly aware that COVID-19 and the resulting shelter in place orders to combat its spread have had a tremendous financial impact on patients everywhere. "Rising unemployment and furloughs have resulted in some patients losing their healthcare insurance entirely or suffering reductions to their coverage," she says. "We are working to leverage our expertise to help solve this problem and have experienced numerous modifications to programs across our portfolio. For example, we are seeing adjustments in supply shipped to our program pharmacy in expectation of volume increases in free goods programs. We are seeing documentation requirements relaxed and submission channels expanded to make it as easy as possible for patients to enroll in support and access programs. We are working in partnership with REMS programs/sponsors to adjust program requirements, with support from the FDA, to allow different modalities of testing and documentation to meet safety requirements while ensuring appropriate access."

Access Going Forward

Ms. Tully says the pandemic has created a national discussion around how to improve patient access to care, even when the patient is viewed as less profitable to the system or unable to afford his or her own care.

"Multiple pieces of legislation have been passed in March that require coverage of critical testing, treatment, and, should they come to market, vaccines, without costs to the patient," she explains. "This behavior in the market may increase costs to the plan in the short term, but it could reduce the overall cost to the system in the long term. These types of value-based approaches will hopefully continue to grow in popularity and adoption across the payer market."

Ms. Tully says an additional change that has taken root within the current environment is the coverage of patient care via non-traditional channels. "The recently enacted Coronavirus Preparedness and Response Supplemental Appropriations Act provides $500 million for an emergency waiver that will expand coverage for telehealth services in Medicare," she says. "The commercial plans have followed, including of Aetna, BCBS, Humana, and others. As our environment has moved to one that is more virtual in nature, these types of changes for telehealth coverage will only support greater patient access to care."

Ms. Douglas believes that the pandemic will lead to the continued evolution of technology-enabled patient-centric access programs.

Managed Access Programs

Often when an investigational medicine for a rare, serious, or life-threatening disease posts promising results in clinical trials, physicians and their patients seek immediate access to the therapy. The term "managed access" covers several types of programs, including compassionate use, expanded access, and named patient supply. The common parameters for involvement in these programs are as follows:

- The patient in question has a life-threatening or serious condition for which there is no viable therapeutic alternative.
- The patient is not eligible for a clinical trial of the investigational medicine.
- The patient's physician has confirmed that the benefit of the treatment outweighs the potential risk.
- The administration of the treatment to the patient will not interfere with ongoing clinical trials.

Most, if not all, of the large, mid-size, and small pharma, biopharma, and biotech companies have some type of managed access programs in place. Patients and caregivers can easily find information on company websites that detail the programs as well as how to request access.

"We anticipate further adoption of our kind of model, including virtual consultations and interactions between clinicians and patients, and less dependence on hospitals and clinics for both trial and treatment interventions," she says. "We think in the future there will be greater acceptance of the viability and validity of access programs that today are seen as the exception rather than the rule."

Mr. Johnson sees improved use of digital tools to shorten the process of benefits investigation and enrollment into patient support programs on the horizon for patient access.

"Even today, many healthcare provider office staff are still bogged down in the process of faxing — yes, faxing — forms for the aforementioned activities," he says. "As a result, there are often delays in obtaining insurance approval and initiating therapy. Automation of this process can save time and money, and in certain cases can be accessed and started by the physician while in the electronic medical record workflow."

Because of COVID-19, patient-support programs are trending toward providing innovative approaches that empower patients and improve their experiences in order to improve adherence to therapy.

RAYMOND JOHNSON
Ogilvy Health

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NATALIE DOUGLAS
RareiTi

According to Ms. Douglas, she and her co-founder Wendy White created RareiTi to help meet the growing demand on the biopharma industry to respond to the unmet needs of rare disease patients and physicians, as well as their communities. "Speeding access to therapies in parts of the world where a license may take longer to come by can be assisted by an early access program delivered within a regulatory framework," she says. "Managed access programs can also support patients once the drug is registered, providing patients and their families with support beyond therapy and drug companies with real-world intelligence."

Mr. Johnson also sees intelligence as an area where patient access is evolving in the near term. "Data from digital therapeutics — DTx — once synthesized and analyzed, have the potential to help inform more tailored and targeted outreach to support patients," he says. "In partnership with specialty and retail pharmacies, there may be an opportunity to leverage insights from DTx data on patient behavior and outcomes, to improve understanding of the value that a therapy provides. Furthermore, those data and insights could be helpful to inform when and how to communicate that value to patients in an impactful way, resulting in improved adherence, and, ultimately outcomes."

Mr. Johnson believes a quote from former U.S. Surgeon General C. Everett Koop, M.D. is still relevant today: "Drugs don't work in patients who don't take them."

"Right-touch, personalized programs can help to strengthen patient engagement, meeting the patient at those moments of truth where they are along the treatment journey and providing clarity around the value of adhering to treatment," he says. "Thoughtful and purposeful two-way communications with patients can create a robust stream of useful data on patient behaviors during those moments of truth and help to crack the code on how best to continuously improve future patient engagement."

Patients at the Center

Before the pandemic, in January 2020, several pharma and biotech executives released a "New Commitment to Patients" pledge designed to affirm and strengthen the industry's commitment to patient-centric treatment. Many believe managed access programs fit neatly into the pledge's vow to "invest only in novel therapies that address unmet patient needs" and to "commit to patient advocacy in how we build and operate our companies, and to connecting directly with patients and their families."

Mr. Johnson notes the pledge provides a rallying cry for the moral obligation to develop the best medicines and ensure that every person who may benefit has access to them.

"Its intent addresses both access and affordability for treatments that these small and midsize biotechs develop, and in some cases market," Mr. Johnson says.

However, he adds, the industry is still waiting for the authors of the pledge to provide details related to the overall approach, as well as next steps for making the promises reality. "It may be a telling sign that many of the large biotech and pharma companies are notably missing from the list of those that affixed their signatures to the pledge as author or co-signer," he observes, adding that representation from a full complement of manufacturers is needed for true fulfillment of the pledge.

Mr. Johnson also believes multiple industry stakeholders across payers and pharmacy benefit managers, wholesalers, retail and specialty pharmacies, and others have to work together to develop a viable, coordinated plan to address the basic goals of the pledge: patient access and affordability and responsible pricing for the therapies at launch and into maturity.

It is important to continue ensuring patient access once products are on the market. Ms. Tully says she and her team strive to quickly understand the impact to the healthcare ecosystem and help customers and providers to better manage and navigate patient access and care. "Our approach is not just based on anticipated trends, but on actual experiences that are happening in our clinics, our pharmacies, and our access programs as they manage payer, provider, and patient challenges," she says. "The information is immediate and from the front lines of care."

Ms. Douglas believes the pledge is a fantastic initiative to bring collective industry efforts together as one. "How else can we bring the essential component of the patient into every stage of the medicines development life cycle?" Ms. Douglas asks. "I would say our philosophy and approach is an endorsement of the pledge and those who have committed to make the necessary changes to drive it through the industry." PV