The use of prescription medications to prevent and treat illness and disease is a crucial component of modern medicine.

From antibiotics to treat bacterial infections to vaccines for infectious diseases and medications for countless health conditions, prescription medications play a vital role in the U.S. health care system.

In fact, nearly half of Americans have used at least one prescription drug in a given month in recent years, according to the Centers for Disease Control and Prevention. In 2019, about 80% of physician practice visits involved drug therapy, with one billion drugs provided or prescribed.\(^1\)

The effectiveness of medications, whether prescribed or over the counter, requires that they be used safely and responsibly—particularly with prescription medications, which can only be prescribed by a licensed health care provider to a designated individual to minimize their potential for harm.

**AHEAD OF THE CURVE**
Federal and state laws closely regulate the distribution and use of prescription medicines. Clinical and pharmacy guidelines help ensure their safe and appropriate use. These rules can vary according to how the Food and Drug Administration (FDA) categorizes prescription drug products. For instance, specialty pharmacy products often require more rigorous clinical monitoring, with stricter controls and handling requirements, due to their potential for more severe side effects and other reasons.\(^2\)

One important category of specialty
pharmacy products is biologic medicines, which encompass a range of medications, products, and therapies. These include vaccines, gene therapy, somatic cells, tissues, treatments involving blood components, and recombinant therapeutic proteins. Biologics are distinguished by their use of living systems—such as microorganisms, plants, or animal cells—in their production.

Biologics often refer to protein molecules that target immunological processes and inflammatory disease responses. A relatively newer group of medicines, biologics are typically administered as injections or infusions.

As specialty pharmaceuticals, much of the growth in biologics—or related bi-similar products—has occurred over the past 20 years. Today, biologics are increasingly used in dermatology, rheumatology, allergy, asthma, immunology, orthopedics, and oncology. And the selection of biologic medications to choose from is growing. For example, at least 11 FDA-approved biologics are now available to treat psoriasis, and over 25 new biologics are being developed to treat eczema. In 2022, 40% of all new drugs approved by the FDA were biologics.

FIRST STEPS

Acquiring access to prescription biologics can often be complicated for patients. Insurance health plans typically require patients to meet prior authorization rules to receive them. These requirements can involve meeting what are known as step therapy rules that require the patient to have first tried and failed other treatments before a biologic prescription can be approved. For some patients, a high co-pay or lack of insurance can also be barriers to access.

Accordingly, medical practices may assign staff to manage prior authorizations and other tasks related to the approval process. Especially in dermatology, rheumatology, allergy, asthma, and immunology, they may assist providers and patients as biologic coordinators. These employees are often essential in helping navigate insurance and coverage issues to secure patient access to prescribed biologics or other specialty medications.

Who can be a biologic coordinator?

“The coordinator position can be filled by a medical assistant, licensed practical nurse, physician assistant, practice manager, physician, or other health care professional,” says Lacey Varnon, ADN, PACS, BCPA, founder of the National Society of Biologic Coordinators.

Whatever their background, the biologic coordinator should possess strong communication skills, basic familiarity with the biologic medications used in the practice, and knowledge of the insurance rules relevant to obtaining prescription benefits coverage.

Notably, practice staff and others responsible for managing prescription access responsibilities may function under different job titles, reflecting the newness of the biologic coordinator position in health care. “The biologic coordinator role can go by so many different names,” explains Varnon. “It’s not always necessarily called a biologic coordinator. Sometimes, it is called a medication access specialist. Sometimes, it’s a physician or a nurse who is in this role. It doesn’t necessarily have to have a specific title; it’s just that medication access position, whoever is in the [practice] getting that work done.”

Those who work as biologic coordinators know that securing biologics and similar drugs can be time-consuming, notes Heather Sawrey, cofounder and president of Biologic Coordinators of Dermatology.

“Once we get the medication approved, the next challenge is [whether] the patient [can] afford the medication,” she notes. “These medicines are usually expensive, and the normal co-pay for a commercially insured patient can be hundreds of dollars. For the Medicare patient, the co-pays are usually over $1,000. As biologic coordinators, we help commercially insured patients enroll in the co-pay card programs [manufacturer cost-savings programs], and we can help Medicare or uninsured patients get directed to the patient assistance programs for their situation. Once we get them signed up for the respective co-pay assistance, we get the prescription sent to the specialty pharmacy for the patient.”

Sawrey adds that many patients may be unaware of what a specialty pharmacy is. “We take the time to explain why the prescription cannot go to their normal neighborhood pharmacy,” she remarks. “We also explain how the pharmacy will call and set up a delivery once their new patient enrollment has been taken care of. As a biologic coordinator, we also make sure they know how [and when] to inject their medication if it is an injectable.
We also set up the training appointments and make a dosing chart for the patient. In addition, we help make sure that the patient has follow-up appointments, which can help us with future approvals when we have current notes for the patient. We also can send in refills and do prescription clarifications when the pharmacy may need them.

A biologic coordinator should be extremely detail-oriented with good time-management skills, adds Varnon, a Tennessee-based program manager for Allergy Partners, a national allergy and asthma practice. “As a manager, my goal is for the [physician] to prescribe the drug they want, and the coordinator works to obtain that drug. … But it’s not as simple as sending out an authorization request and moving forward with whatever happens. It’s about diving down and getting to the bottom of what’s happening in the process—being that detailed investigator who can ensure the patient gets the drug that’s been prescribed.”

Notably, the biologic coordinator’s job will partially depend on how practices manage pharmacy requests. Varnon explains that some hospital clinics and physician practices use the buy-and-bill reimbursement model, managing their own inventory of medications that they purchase and sell directly to patients. The buy-and-bill model makes it possible for practices to maintain greater inventory control and access to many medications they prescribe.9

“Our role as biologic coordinators is going to depend on how the drugs are acquired,” says Varnon. “The benefits investigation is the very first thing we always do, which is going to be that deep dive into the insurance and the coverage value. Then we submit the authorization request, based on how we need to acquire the drug, whether it’s buy and bill or specialty pharmacy.”

Like Sawrey, Varnon takes a methodical approach to fulfilling the prescription request. “We could have a severe asthmatic patient, for example, that the [physician] decides to put on TEZSPIRE [tezepelumab-ekko]. First, we will have the enrollment form filled out by the patient in the office. Then, our team will do our own [internal] benefits investigation, which involves several steps. We’ll ask whether this prescription is covered under medical insurance or pharmacy benefits. In my benefits investigation, I also look at the patient’s responsibility: Is the drug going to be affordable for them? [Some] co-pay assistance programs exist, but they’ll need to be eligible. Then, after we get all this information back, we will submit a medical benefit prior authorization to the medical insurance or the payer.”

How does Varnon handle claims denials? “When you get a denial, it’s a matter of pleading your case,” she says. “You want the insurance payer [to] understand why the patient needs this drug and its benefits. One thing I find helpful is to use my own fill-in-the-blank templates for different types of appeals. This can make the process a little faster.

“Another thing I find helpful is to quote the insurance company’s own words in my appeal letter. So, whatever their policy states, use their language and make sure to include the [insurance] policy number in the appeal. It helps if the payer realizes that you’re doing the work behind the request and are looking at this closely.”

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“Biologic Coordinators of Dermatology—BCoD—is an association of over 2,000 members aimed at enhancing the patient journey by educating and empowering the biologic coordinator, medical assistant, or office staff overseeing drug fulfillment. “Our annual conference brings together members and industry partners who share in the relentless pursuit of patient access.”

“Last year’s meeting unveiled the BCoD certificate program that offers the most relevant and meaningful patient access content available in the industry. We are steadfast in providing our members with a deep network of resources. In 2024, BCoD will unveil additional resources suited for seasoned and newer access staff so they can efficiently and confidently move the patient through their therapeutic journey.”

—Craig Schuette, Executive Director of Biologic Coordinators of Dermatology

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“[There] are so many different avenues now for us; there should not be many reasons why we cannot get a patient started on the product the physician prefers. We all know [insurance] appeals and denials are a huge issue in health care. But a successful biologic coordinator will understand how to get around these issues.”

—Lacey Varnon, ADN, PACS, BCPA
medications are generally not tier 1 [medications] but the higher 3-, 4-, or 5-tier medications.”

Prescription drug formularies often have tiers or groups of drugs categorized by cost. Accordingly, the patient’s co-payment or cost-share is based on which tier the drug is in. “The insurance company usually wants to start with the least expensive tier drug—[for example,] 1, 2, 3, or 4—and work up to tier 5,” says Evans. “The prior authorization process is a way for them to justify why the patient needs the prescription.”

Evans makes another crucial point about the approval process. “There are two parts to a prior authorization,” she explains. “For most people with health insurance, there is almost always a prescription coverage benefit plan within that health insurance. I might have Blue Cross Blue Shield, but my prescription coverage is CVS Caremark, Express Scripts, or Optum Rx. The patient’s insurance company [does not usually approve or decline] the request. This is done by the prescription benefit plan. So, your first step with a prior authorization request will be to know where to go for the approval.”

Evans notes that the patient’s insurance card will usually have a BIN, PCN, and group number, as well as a member ID, which can help identify the company responsible for the prescription drug coverage. For those working in primary care or internal medicine, Evans also suggests staff avoid overlooking supporting documentation from other providers. “In many cases, the supporting documentation for prior authorizations is important,” she states. “For example, obtaining notes from the patient’s rheumatologist or dermatologist is often helpful to include. This is because sometimes medications are prescribed in primary care in conjunction with other specialties.”

With any prior authorization request, documentation is key. “In terms of step therapy rules, you want to make sure you’re diligent with your chart review [to] document failed treatment alternatives,” remarks
Evans. “Maybe the patient didn’t fail a treatment last year, but they could have failed something five years ago. You might have to dig deep for that information.”

**TWISTS AND TURNS**

Managing prior authorization requests can sometimes be complicated by whether the insurer’s request is improper. The Office of the Inspector General reported that 13% of prior authorization denials by Medicare Advantage in 2019 were for covered benefits.¹¹

For staff, countering improper prior authorization requests without access to the patient’s insurance policy can be difficult, according to experts. “Whether it involves biologics or something else, any medical treatment that requires prior authorization is first a matter of understanding what the patient’s insurance policy states,” says David J. Zetter, president of Zetter Healthcare Management Consultants in Mechanicsburg, Pennsylvania.

Unfortunately, Zetter says many medical practices do not access patients’ insurance policies. He explains payers may inappropriately require unnecessary prior authorizations for certain services or treatments.

“Somewhere in the neighborhood of 65% of all new drugs in development are biologics. That’s some big job security for a biologic coordinator. It’s important for medical assistants, nurses, or others to understand that there is a career pathway [to] being a biologic coordinator. But it adds not just a monetary value but also the satisfaction that comes when you are helping patients directly in getting the specialty medications they need.”

—Marc Del Bono, PACS
“Most practices just assume the insurance company is the expert requiring a prior authorization,” remarks Zetter, a past president of the National Society of Certified Healthcare Business Consultants. “Unfortunately, if they request a prior authorization that is not legal, the practice is often not going to know this.”

Most private retirement and employer-based health plans are governed by the Employee Retirement Income Security Act of 1974, the federal law that sets minimum consumer protection standards for the plans.12 Zetter cautions that many medical practices are unversed in the act’s benefits protections.

Notably, the American Medical Association and other groups are critical of insurance industry rules on prior authorization, describing them as often “costly, inefficient, and responsible for patient care delays.”13 In 2022, an American Medical Association physician survey found that about 94% of physicians reported delays in care because of prior authorization requirements. Further, approximately 80% of physicians say patients abandoned recommended treatments because of prior authorization roadblocks. In turn, many surveyed physicians report negative impacts on clinical care and patient outcomes because of these barriers.14

As a result, efforts to legislate reforms in prior authorization practices are now under consideration in many states.

“Prior authorizations are a cost-saving measure for insurance companies,” observes Marc Del Bono, PACS, the former manager of member education with the Biologic Coordinators of Dermatology. “Biologic coordinators are aware of this. We also know there are initiatives for prior authorization reform and discussions looking toward streamlining prior authorizations.” For Del Bono, these challenges only underscore the critical role of biologic coordinators in navigating solutions to access barriers.

“A biologic coordinator is someone who sees through the problem,” he says. “They will go to the Blue Cross Blue Shield portal, for example, and look at the policy to see if a prior authorization is required. If so, what step edits [do] they need to inform the prescriber about? As biologic coordinators, we’re the ones who let the prescriber know what medications need to be tried and failed so we can prevail with the authorization.

When practices don’t have biologic coordinators, the insurance companies win. We are advocating not only for the patient but also for the practice.”

A PATH FORWARD

Biologic coordinators are an emerging professional resource in health care. With increased prescription biologics and other specialty medications, the need for trained staff with expertise in facilitating patient access to specialty pharmacy products is more important than ever.

Medical assistants interested in working as biologic coordinators can find numerous opportunities. “Finding people who can fill the role of a biologic coordinator is a big need now in health care,” concludes Varnon. “I think more providers at the executive level are starting to understand the value behind having someone who is specifically trained as a biologic coordinator, with the knowledge base necessary to do the best work.”

While biologic coordinators manage the prescription enrollment and approval process, they also support and educate patients, answering their questions or concerns regarding benefits or treatments. For instance, a biologic coordinator might provide patients with educational videos on home injections, dosing schedules, or other treatment issues. They also educate prescribers on access issues.

In this sense, biologic coordinators play a unique role as patient advocates, working closely with providers, patients, and insurers to navigate often dense pathways to medication access. Their skills make them a potentially instrumental resource in the patient’s journey to health and healing.
References