Helping Patients Navigate the Specialty Pharmacy Experience

The Purpose of this Fact Sheet

This fact sheet is intended to provide health care professionals and others in patient support roles with an overview of specialty medications and specialty pharmacies so they can better assist patients in navigating the specialty pharmacy journey.

The Growing Specialty Medicine Market

The number of specialty medications has risen quickly and continues to grow at a rapid pace. In the early 1990s, fewer than 30 specialty medications had been approved by the U.S. Food and Drug Administration (FDA). By 2017, more than 400 were on the market. Many more specialty medications are introduced each year.[1] For instance, in 2019, about two-thirds of the novel therapies introduced were specialty medications.[2,3]

Until recently, specialty drugs were only available to treat serious and complex conditions, such as cancer and rheumatoid arthritis. Today, a wide variety of diseases and conditions are treated with specialty drugs. For instance, people with common health conditions, such as asthma and atopic dermatitis, can be helped with specialty drugs.[4] In addition, medicines have been developed to treat serious rare diseases, such as sickle cell disease and hemophilia.[5,6] In some cases, a specialty drug may be the only treatment available for a life-threatening disease.[4]

Specialty medications are broadly defined as high-cost, complex treatments.[7] Many are biologics, which the FDA defines as follows:

> "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies."[8]

Some patients may require biomarker, genomic, or other testing to determine the treatment most likely to result in a favorable response.[9]

Because many specialty medications are more complex than traditional medicines—for example, they require special storage or handling, they may be administered in a variety of treatment settings, and they may require ongoing clinical monitoring—most patients need education about what to expect during treatment.[10]

Medical Breakthroughs

Specialty medications have the potential to improve survival and quality of life for people with many diseases.[11] For instance, drugs used to treat multiple sclerosis help limit new disease activity, can prevent or delay disability, and reduce relapses.[12] In another example, antiviral medicines hat treat hepatitis C, a type of liver disease, have been shown to produce a sustained viral response, indicative of a cure, in about 90 percent of patients after eight to 12 weeks of antiviral treatment.[13]

Gene therapies hold promise to cure or halt the progression of some diseases with a genetic component. Some gene therapies fix or add working copies of a faulty gene inside the cells.[14] Other gene therapies enhance the immune system's ability to recognize and attack cells that are a threat.[15] Currently, only a small number of gene therapies have been approved by the FDA. Many more are being tested, and experts predict many different gene therapies may be available in coming years.[14,16]

The Role of Specialty Pharmacies

Specialty pharmacies were established to procure, store, and dispense specialty drugs.[17] Health plans typically require patients to obtain their specialty medicines through the contracted specialty pharmacies in the plan's preferred network.[18] In addition to dispensing medications, specialty pharmacies provide individualized support and services, including the following[17]:

- Coordinating the claims adjudication process (e.g., benefits investigation, prior authorization)
- Accessing available financial assistance programs offered to patients by drug makers and others
- Providing medication and disease-specific education and counseling in the patient's language of choice
- Shipping medication that requires special handling (e.g., temperature control)
- Providing ancillary supplies
- Coordinating in-home services (e.g., infusion therapy, skilled nursing) as needed
- Offering medication adherence programs
- Arranging medication deliveries
- Identifying potential adherence barriers and managing treatment effects

The high-touch approach that specialty pharmacies use may be responsible for the high rates of treatment adherence documented among patients receiving medication through specialty pharmacies.[19]

Specialty pharmacies are state licensed[10] and are expected to meet a range of performance and quality criteria, such as:

- Accreditation by one or more independent organizations, such as URAC, the Accreditation Commission for Health Care (ACHC), the Joint Commission, or the Center for Pharmacy Practice Accreditation (CPPA)[17,20]
- An organizational structure adequate to support all necessary operations[17]

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- 24/7 patient access to a pharmacist to answer questions and address medication-related issues[7]
- Cold-chain management to ensure proper temperatures are maintained throughout the distribution/dispensing process for products that have a cold-chain storage requirement[17]
- Adherence to disease- and drug-specific clinical and drug safety protocols, including Risk Evaluation and Mitigation Strategies (REMS) required by the FDA[17,21]

Over the past several years, the specialty pharmacy market has become more consolidated and integrated. The largest health insurance companies in the United States — UnitedHealthcare, Aetna, Cigna, Anthem, Humana, and BlueCross BlueShield — either own or are aligned with the largest specialty pharmacies and pharmacy benefit managers (PBMs).[22] In addition, many large hospitals and health systems operate their own specialty pharmacies as part of a coordinated approach to care delivery.[23]

In 2020, 75% of prescription revenues for pharmacy-dispensed specialty medicines were accrued by the four largest specialty pharmacies, all of which provide services remotely, including online or over the phone.[24-28]

In some cases, manufacturers may limit the number of specialty pharmacies that can dispense their medications. In these arrangements, which are called "limited distribution networks," the manufacturers typically choose specialty pharmacies they deem best able to deliver positive patient experiences and health outcomes. For instance, manufacturers of specialty oncology medicines may limit distribution to specialty pharmacies that specialize in cancer. This can represent an opportunity for some smaller specialty pharmacies. If they can demonstrate expertise in specific patient populations or disease states, they can potentially have an advantage over the larger players in the market.[29]

The Patient's Perspective

Accessing medicines through a specialty pharmacy tends to be more involved than filling a prescription at a traditional pharmacy.[30] Patients may be unfamiliar with the steps involved in obtaining a specialty medication, particularly when securing a first fill. They may have questions or concerns about the following issues:

- Navigating the prior authorization process
- Dealing with higher out-of-pocket costs
- Communicating with multiple people
- Accommodating the delivery schedule and location

Navigating the prior authorization process

In an effort to control costs and ensure safe and appropriate utilization, health plans use various utilization management tactics. One such tactic is prior authorization, which is when a health plan must issue an approval before a medicine or health service will be covered by the plan.[31,32]

The prior authorization process can require the submission of information that is not readily available from electronic claims sources.

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The time to obtain and evaluate clinical information, such as the patient's clinical diagnosis, weight and height, lab results, and nondrug therapies, can delay a prescription fill by days or even weeks.[32,33] This can sometimes lead to prescription abandonment. One report found that 37% of prescription medicines that were initially denied under prior authorization were abandoned by patients.[34] That is why it's important to educate patients about the time, effort, and paperwork that may be involved in obtaining the medication.[35]

Specialty pharmacies often manage prior authorization requests for prescribing providers.[36] If a health plan denies the prior authorization request, the prescribing provider can submit an appeal with additional information that further details why the medication is medically necessary.[37]

Health plans use other utilization management tactics as well. In some cases, the health plan may require patients to try a different medication(s) first, such as a less costly drug that has been shown to be an effective treatment, before agreeing to cover the specialty medication. This is known as step therapy. The prescribing provider can file a step therapy exception by explaining why a patient needs to take the requested specialty medicine prior to having taken the other medicine first.[38]

Health plans may also set quantity limits on specialty medicines, or only cover a certain quantity of the medicine for a limited period of time (for example, one pill a day for 30 days).[38]

Dealing with Higher Out-of-Pocket Costs

A patient's out-of-pocket costs for specialty medications can be substantial.[39] Most health plans require patients to contribute to the cost of drugs, and a patient's out-of-pocket cost is dependent on the drug's placement on a formulary tier. Most specialty drugs are in "specialty tiers," which have the highest cost-sharing requirements (i.e., copayment or coinsurance amounts).[40] Most patients also must satisfy an annual deductible each year before their health plan begins paying for drugs or services.[41] Health plans usually only start to pay 100% of a drug's cost after a patient's annual out-of-pocket maximum is reached.[42,43]

In general, self-administered medications (i.e., oral medicines, self-injectable drugs) are covered under a health plan's pharmacy benefit, while those administered by a health care provider (e.g., infusions) are usually covered under the medical benefit.[39]

In addition to cost-sharing, other health plan strategies that can impact patients' out-of-pocket costs include:

- **Use of generic or biosimilar versions:** Using generic or biosimilar versions of specialty medications can cost patients less out-of-pocket than brand-name drugs.[44] (For more information, see the sidebar "Biosimilars Versus Generic Drugs" on page 5.)
- **Site of service optimization:** For specialty medications that need to be administered by a health care provider (e.g., infusible drugs), health plans may steer members away from obtaining their medicine in hospital outpatient centers (e.g., ambulatory infusion center, home infusion), which are more costly than other sites of care.[45,46]
- **Drug dosing strategies:** In some cases, making small changes to a patient's specialty medication regimen, such as lowering the dose or the frequency of dosing, can reduce a patient's out-of-pocket costs while attaining the same clinical outcomes.[45,47]

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High out-of-pocket costs can sometimes lead to patients not filling their prescriptions.[48] When patients cannot afford their specialty medications, specialty pharmacies may be able to connect them to patient assistance programs offered by drug manufacturers and other organizations.[17,49]

One type of financial aid offered by drug manufacturers is copay support. Patients with commercial insurance can receive copay support, but patients with government insurance (e.g., Medicare, Medicaid) are not eligible. Normally a manufacturer's copay support payments count toward a patient's deductible and out-of-pocket maximum. Once these limits are reached, the health plan pays for all subsequent prescriptions.[50,51]

Copay support from drug manufacturers can help make specialty medications more affordable for patients. However, many commercial health plans now use copay maximizer and copay accumulator programs — which shift the plan's cost back to the patient or the manufacturer and, thereby, decrease the overall benefit of copay support for the patient. Below is more information on these programs[50,51]:

- Copay maximizers: Copay maximizer programs evenly apply the maximum value of the manufacturer's copayment program at each fill, throughout the benefit year.
- Copay accumulators: Copay accumulator programs do not allow copays funded by the manufacturer's support program to count toward the patient's annual deductible or out-of-pocket maximum.

Biosimilars Versus Generic Drugs

Generic medicines are very common. Generic drugs account for 90% of prescriptions filled in the United States.[52]

But what are biosimilars and how do they differ from generic medicines?

In a nutshell, generic drugs are equal substitutes for traditional brand-name drugs,[53] while biosimilars are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product.[44]

Pharmacists can substitute generic drugs for the brand-name version without consulting the prescribing provider, although most states require pharmacists to check with the patient first.[54] However, biosimilars need to meet additional requirements and must be deemed "interchangeable" by the FDA before a pharmacist can substitute a biosimilar for its brand-name counterpart without the permission of the prescribing provider. In addition to being a biosimilar, an interchangeable product is expected to produce the same clinical result as the reference product in any given patient.[44]

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The table below provides more details on generics and biosimilars.

Traditional medicines (e.g., antibiotics, high blood pressure medicines): These drugs are made by combining specific chemicals to create a drug. Thus, these drugs can be identified by their chemical structure.[55]

Generic drugs: A generic drug contains the same active ingredient(s) and consists of the same strength and dosage as its brand-name counterpart. The manufacturer must demonstrate that the generic is bioequivalent to the brand-name drug.

Generics are considered as safe and effective as the existing brand-name drugs but are usually less expensive.[53]

Certain specialty drugs that are traditional medicines may have generic versions available. For example, generic versions of two anti-viral specialty medicines that treat hepatitis C are now available.[56]

Biologics: These drugs are derived from natural sources (i.e., human, animal, microorganism). They may be living entities (e.g., cells, tissues) or made of proteins, nucleic acids, or sugars. They are produced via biotechnology or other leading-edge technologies.[8]

Unlike traditional medicines, biologics are difficult to define by a chemical structure.[57] In addition, because these drugs are developed from natural sources, there are intrinsic variations that can occur during manufacturing. Small variances between manufactured lots of biological products are anticipated and normal. The FDA assesses the production control strategies that biologic manufacturers put in place to ensure reliable clinical performance.[44]

Biosimilars: A biosimilar is highly similar to an existing brand-name reference drug.

Manufacturers must demonstrate that there is no clinically meaningful difference between biosimilar and reference drugs—in terms of effectiveness, purity, or safety. However, minor differences in clinically inactive ingredients (e.g., stabilizers, buffer) may exist between the biosimilar and the brand-name reference drug.[44]

Many specialty medicines are biologics, and a growing number of biosimilars are available. As of September 2021, the FDA had approved 31 biosimilar drugs.[58]

Communicating with Multiple People

Patients being treated with a specialty medication are likely to be in contact with multiple people from the specialty pharmacy, including pharmacists, insurance coordinators, nurses, and patient care coordinators. At the same time, they may be fielding phone calls, responding to texts, and managing communications from the health provider's office, home health agency, health plan care manager, and others.[59]

The high number and varied nature of these communications may leave patients feeling exhausted and confused.

Determining Where the Medication Will Be Delivered

Specialty medicines can be delivered to a variety of locations, some of which may not be the patient's home. Where the medication is sent varies based on certain factors.

For oral, self-injectable, and other medications that patients can take on their own: These medications will likely be shipped to the patient. In some cases, patients may be able to pick up the medication at a local pharmacy.[49,60,61]

The specialty pharmacy may also provide the supplies needed to take the medicine, such as alcohol pads, syringes, and needles for injectable medicines.[60]

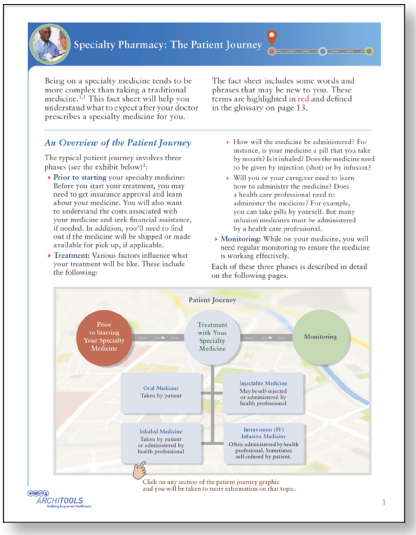
For infusions and other medicines that need to be administered by a health care professional either at the patient's home or at a hospital, doctor's office, or outpatient facility: These specialty medicines may be delivered in a variety of ways:

- The health care provider may purchase the medicine and store it until the patient's scheduled appointment. This approach is known as "buy-and-bill" because the provider buys the medicine and then bills the patient's insurance medical benefit.[62]
- The specialty pharmacy may ship the medicine to the patient. This approach, known as "brown bagging," makes the patient responsible for properly storing and transporting medicines that may require refrigeration or other special storage.[63]
- The medication may be filled by a specialty pharmacy that collects needed copayments or coinsurance and settles the claim with the payer. The medication is sent directly to the provider to prepare and dispense. This is known as "white bagging."[63]
- A site of care with its own specialty pharmacy may dispense the medicine at the time of the patient's treatment(s). This approach is called "clear bagging."[63]

Steps You Can Take to Guide Patients

As someone who works directly with patients, you are in a unique position to help them make the most of specialty pharmacy services.

Here are some ways to consider using the ArchiTools Specialty Pharmacy Toolkit to help your patients.


Specialty Pharmacy: The Patient Journey

Being on a specialty medicine tends to be more complex than taking a traditional medicine.[1,2] This fact sheet will help you understand what to expect after your doctor prescribes a specialty medicine for you.

The fact sheet includes some words and phrases that may be new to you. These terms are highlighted in red and defined in the glossary on page 13.

An Overview of the Patient Journey

The typical patient journey involves three phases (see the exhibit below)[3]:

- Prior to starting your specialty medicine: Before you start your treatment, you may need to get insurance approval and learn about your medicine. You will also want to understand the costs associated with your medicine and seek financial assistance, if needed. In addition, you'll need to find out if the medicine will be shipped or made available for pick up, if applicable.
- Treatment: Various factors influence what your treatment will be like. These include the following:
  - How will the medicine be administered? For instance, is your medicine a pill that you take by mouth? Is it inhaled? Does the medicine need to be given by injection (shot) or by infusion?
  - Will you or your caregiver need to learn how to administer the medicine? Does a health care professional need to administer the medicine? For example, you can take pills by yourself. But many infusion medicines must be administered by a health care professional.
- Monitoring: While on your medicine, you will need regular monitoring to ensure the medicine is working effectively.

Each of these three phases is described in detail on the following pages.

Patient Journey

Prior to Starting Your Specialty Medicine

Treatment with Your Specialty Medicine

Monitoring

Oral Medicine Taken by patient

Injectable Medicine May be self-injected or administered by health professional

Inhaled Medicine Taken by patient or administered by health professional

Intravenous (IV) Infusion Medicine Often administered by health professional. Sometimes self-infused by patient.

Click on any section of the patient journey graphic and you will be taken to more information on that topic.

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Give patients an overview of the specialty pharmacy journey

Educate patients about what they can expect by giving them the patient education resource, "Specialty Pharmacy: The Patient Journey," available on ArchiTools. This literacy adjusted, easy-to-follow piece lists the common steps on the journey, reviews the most frequent challenges, and offers tips on how to navigate through them.


More than Medicines: The Role of Specialty Pharmacies

Introduction

Your doctor has prescribed a medicine that must be filled by a specialty pharmacy. This fact sheet provides some basic information about specialty pharmacies. It will help you learn about and use the services and supports that specialty pharmacies provide.

This fact sheet includes some words and phrases that may be new to you. These terms are highlighted in red and defined in the glossary on page 5.

What Is a Specialty Pharmacy?

Specialty pharmacies dispense (fill) specialty medicines (see box to the right). In addition, specialty pharmacies provide guidance and support to patients 24 hours a day.[1] They help people with a variety of health problems, ranging from rare or complex diseases to more common conditions.[1,2] Conditions that are treated with specialty medicines include[2,3]:

- Asthma
- Cancer
- Rheumatoid arthritis
- Multiple sclerosis
- Hemophilia
- HIV/AIDS
- Growth hormone deficiency
- Cystic fibrosis

Some specialty pharmacies are located in hospitals, medical offices, retail stores, or elsewhere.[4] But many of the large specialty pharmacies provide their services remotely. Most of your contact with pharmacy staff will be over the phone, by email, by text, or on the pharmacy's website or mobile app.[4,5]

What Are Specialty Medicines?

Specialty medicines typically have one or more of the following features[1,5,6,11]:

- They treat serious and complex conditions, such as rheumatoid arthritis and cancer. They are also used to treat rare diseases, such as hemophilia and sickle cell disease.
- Many are biologic products. Biologic products are derived from a variety of natural sources (human, animal, or microorganism). They may be produced by biotechnology and other leading-edge technologies.
- They often need special storage and handling.
- They may require more patient education and monitoring from a health care provider than other medicines.
- Most cost more than traditional medicines.
- They are not commonly dispensed at local retail pharmacies. These pharmacies cannot typically provide the additional patient education or special storage and handling needed with specialty drugs.

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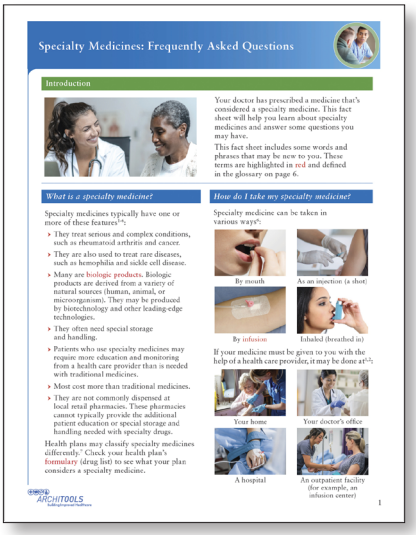
Help patients understand the role of the specialty pharmacy

Patients getting specialty drugs can expect to be contacted by an assortment of people from various organizations, at different points in the treatment process. You can help patients prepare for this by giving them a copy of "More than Medicines: The Role of Specialty Pharmacies,"available on ArchiTools. This tool defines key terms, helps patients understand the services available from the specialty pharmacy, provides tips on keeping an up-to-date health record, and gives guidance on when to reach out.


Specialty Medicines: Frequently Asked Questions

Introduction

Your doctor has prescribed a medicine that's considered a specialty medicine. This fact sheet will help you learn about specialty medicines and answer some questions you may have.

This fact sheet includes some words and phrases that may be new to you. These terms are highlighted in red and defined in the glossary on page 6.

What is a specialty medicine?

Specialty medicines typically have one or more of these features[1-5]:

- They treat serious and complex conditions, such as rheumatoid arthritis and cancer.
- They are also used to treat rare diseases, such as hemophilia and sickle cell disease.
- Many are biologic products. Biologic products are derived from a variety of natural sources (human, animal, or microorganism). They may be produced by biotechnology and other leading-edge technologies.
- They often need special storage and handling.
- Patients who use specialty medicines may require more education and monitoring from a health care provider than is needed with traditional medicines.
- Most cost more than traditional medicines.
- They are not commonly dispensed at local retail pharmacies. These pharmacies cannot typically provide the additional patient education or special storage and handling needed with specialty drugs.

Health plans may classify specialty medicines differently.[1] Check your health plan's formulary (drug list) to see what your plan considers a specialty medicine.

How do I take my specialty medicine?

Specialty medicine can be taken in various ways[6]:

By mouth

As an injection (a shot)

By infusion

Inhaled (breathed in)

If your medicine must be given to you with the help of a health care provider, it may be done at[6,7]:

Your home

Your doctor's office

A hospital

An outpatient facility (for example, an infusion center)

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Guide patients as they learn about specialty medicines

The "Specialty Medicines: Frequently Asked Questions" patient education resource available on ArchiTools provides simple explanations for questions such as "What is a specialty medicine?," "Where can I get my specialty medicine?," and "What if I can't afford them?" Consider providing this resource to patients as a way to reinforce the education you provide to them.

The Importance of Communication

Medication adherence is particularly important with specialty medications and is facilitated by open communication among patients, specialty pharmacies, and providers.[64] Encourage patients to be proactive in reaching out to the specialty pharmacy with questions or concerns.

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