



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.

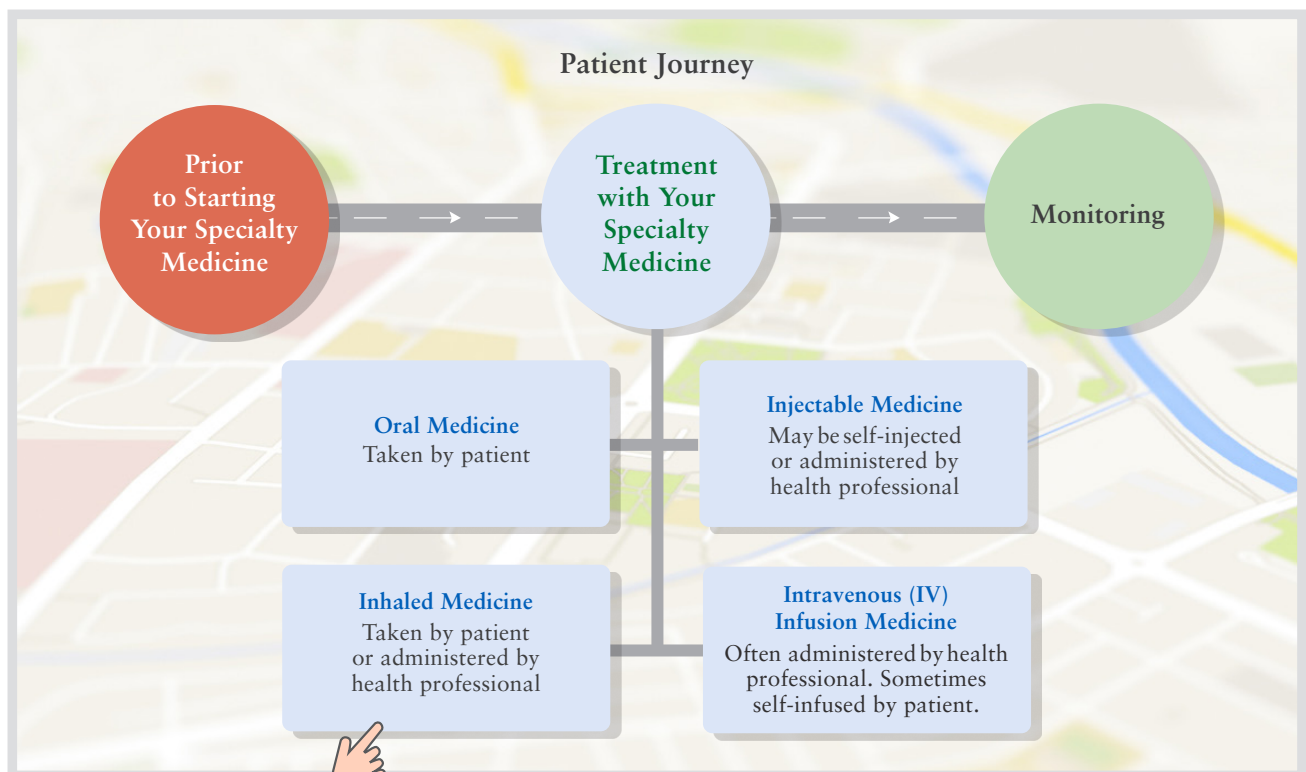
An Overview of the Patient Journey

The typical patient journey involves three phases (see the exhibit below)²:

- ▶ **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.



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



What Makes Specialty Medicines More Complex than Traditional Medicines?

Several factors can make being treated with a specialty medicine more involved than a traditional medicine²⁻⁶:

- ▶ Patients who use specialty medicines may require more education and monitoring from a health care provider than are needed with traditional medicines.
- ▶ Many specialty medicines are **biologic products**. Biologics are derived from a variety of natural sources (human, animal, or microorganism). They may be produced by biotechnology and other leading-edge technologies.
- ▶ Specialty medicines may require special storage and handling.
- ▶ Many specialty medicines must be given by injection (shot) or infusion, sometimes in a doctor's office or hospital. However, some are pills or tablets that can be taken by mouth. Others are inhaled.
- ▶ Specialty medicines tend to cost more than traditional medicines. Depending on your health plan's requirements, you may need to go through extra steps to ensure the drug is covered by insurance. (See "Obtaining insurance approval" section on page 4.)
- ▶ Specialty medicines are not commonly dispensed at local retail pharmacies. These pharmacies cannot typically provide the additional patient education and monitoring you may need. In addition, retail pharmacies may not be able to provide the special storage or handling that specialty drugs may require.

The Role of Specialty Pharmacies

Your health plan may have you use a specialty pharmacy to obtain and manage your drug therapy.⁷ Specialty pharmacies do much more than fill prescriptions. Pharmacists, nurses, and other staff at the specialty pharmacy are available to guide and help you before and after you start on your medicine.⁸ They offer many services, including:

- ▶ Helping ensure payment coverage for your medicines. This can include working with your insurance as well as looking into other coverage options for your medicine.⁸
- ▶ Packaging and shipping the medicines. Pharmacy staff will make sure the medicine is delivered according to any special handling or refrigeration requirements. They will also make sure you have the supplies you need to take the medicine, such as syringes and needles.⁹



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continued from page 2

- ▶ Helping make sure you know how to take your medicine.¹
- ▶ Reviewing all the medicines you take (and why) to help prevent **drug interactions**.¹⁰
- ▶ Counseling you about possible side effects.²
- ▶ Checking in to see how you are doing on the medicine.²
- ▶ Collaborating with your doctor to address any concerns, such as side effects.⁸

- ▶ Sending reminders to refill your medicines.³
- ▶ Providing 24/7 access to pharmacists or nurses who can help with questions and concerns about your medicines or your disease.⁸

Many specialty pharmacies operate remotely, by phone or online.¹¹⁻¹⁵ Some are located in hospitals or elsewhere in communities.^{16,17}





Before Starting Treatment

Your specialty pharmacy will help you obtain and get started on your specialty medicine.⁸ Below are five common steps in the pre-treatment journey. However, each patient's journey may be different. You may skip some of these steps or need to undergo additional steps. It depends on what your doctor or specialty pharmacy recommends.

Learning about the medicine your doctor has prescribed



It's important to know what to expect during treatment. Reviewing the following questions with your doctor or specialty pharmacist can help make sure you have all the information you need¹⁸:

- ▶ What is the name of the medicine?
- ▶ What medical condition does this medicine treat?
- ▶ How often do I take the medicine or get it administered?
- ▶ How long will I have to be on the medicine?
- ▶ How much medicine should I take?
- ▶ Should I take the medicine with food or not? Is there anything I should not eat or drink when taking this medicine?
- ▶ How long will this medicine take to work?
- ▶ Will this medicine cause problems if I am taking other medicines?

- ▶ Is it safe for me to drive while I'm on this medicine?
- ▶ If I forget to take my medicine, what should I do?
- ▶ What side effects can I expect? What should I do if I have a problem?
- ▶ Will I need a refill? How do I arrange that?

Obtaining insurance approval

Your health plan is likely to have processes in place that help ensure the medicines you take are safe, appropriate, and affordable. As a result, **prior authorization** (approval) of your specialty medicine may be required.^{19,20}

During this process, your health plan will likely work with your doctor and specialty pharmacy to get additional medical information. This can help the plan understand why the medicine is medically necessary for you. This information will then be evaluated against your plan's coverage guidelines to determine if coverage is appropriate for your disease or condition.²⁰

It may take days or weeks for your health plan to make a coverage determination. This will likely come in the form of either an approval or a denial of coverage²¹:

Approval: If prior authorization results in a coverage approval, then the health plan will cover the medicine.¹²

Sometimes you may be required to try a less costly medicine first, before a more costly medicine is covered. This is known as **step therapy**.²²

In some cases, health plans may place quantity limits on a medicine. This means the plan limits the amount of medicine they will cover over a certain period of time (for example, one pill a day for 30 days).²²

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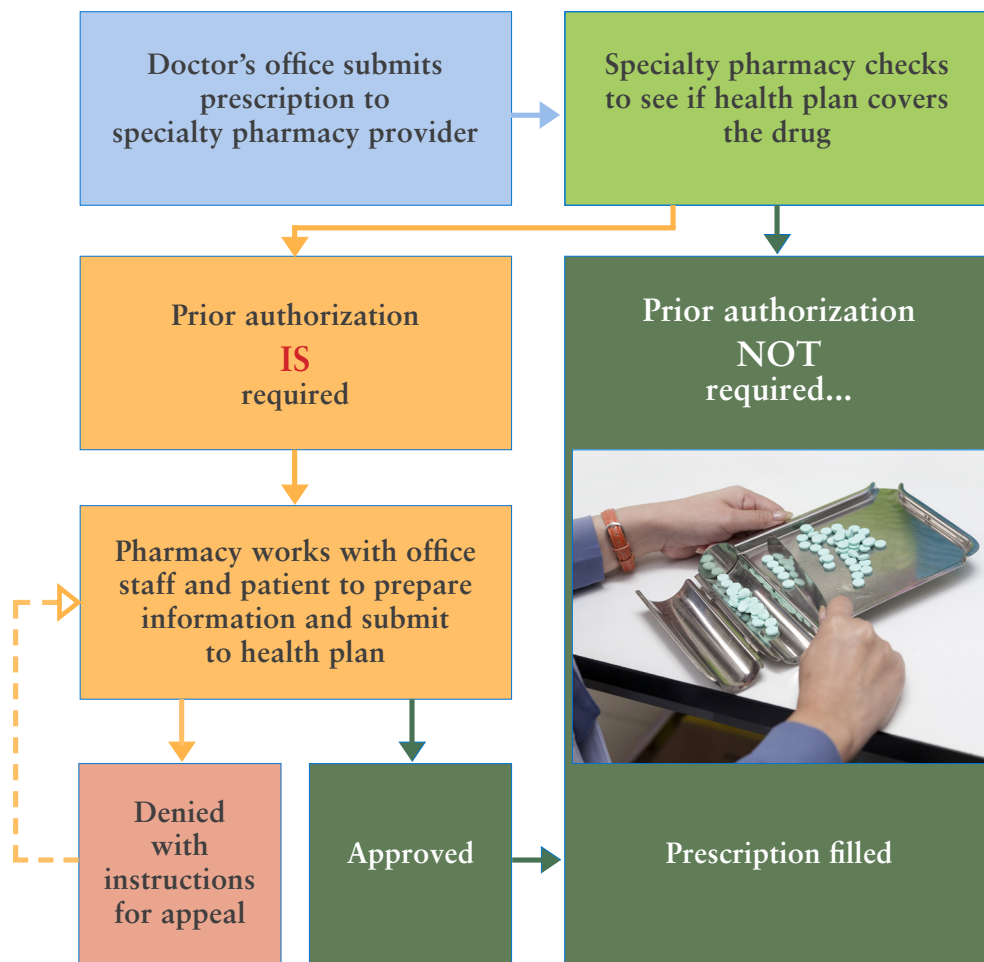
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Denial: If your health plan issues a denial, there may still be some options available to you:

- ▶ Your specialty pharmacy may be able to help you and your doctor identify an alternative medicine that is covered by your health plan.²³

- ▶ You have a right to appeal the denial. Your health plan is required to explain how you and your doctor can appeal the denial decision.¹⁹ Your specialty pharmacy may assist with this process, too.

The Prior Authorization Process^{12, 19-23}





Understanding treatment costs

How much you pay **out-of-pocket** for specialty medicines will depend on your health plan's coverage. Most health plans maintain a list of drugs they cover, called a formulary. Covered drugs are placed into different "tiers," with each tier costing a different amount.²⁴ Most health plans put specialty drugs in the higher cost tiers.²⁵

Health plans usually have other payment requirements as well. For instance, your drug costs may be higher until you have met your plan's **deductible** and may go down when you reach your **out-of-pocket limit**.²⁶

Your specialty pharmacy or health plan may suggest ways to lower your costs, including the following:

Taking a lower-cost medicine: For instance, some specialty medicines have **generic** or **biosimilar** versions available:

- ▶ A generic drug has the same active ingredient as a brand-name drug.²⁷
- ▶ A biosimilar is a biologic product that is highly similar to a biologic product approved by the U.S. Food and Drug Administration (FDA).²⁸

Generic and biosimilar versions may cost you less out-of-pocket than brand-name drugs.²⁸⁻³⁰

Getting care in a less costly site: Most infused specialty medicines must be administered by a health care professional. Infusion care delivered in a hospital-based setting—both inpatient and outpatient—costs the most. You may be encouraged to obtain infusion care in a less costly setting, such as in your doctor's office or a free-standing infusion center.^{31,32}

Exploring financial assistance, if needed.

If you cannot afford your medicine, specialty pharmacy staff may be able to help you. They can help determine if you may be eligible for patient assistance programs. These programs are provided by drugmakers and other organizations.^{33,34} Your state, county, or local government may also have programs that can help you.³⁵

Obtaining the medicine

Your specialty pharmacy will determine if your medicine will be provided to you or to your health care provider. Some medicines are delivered to a location (for example, your home or an infusion clinic). Other medicines can be picked up at a pharmacy.^{19,16,34,36} How you obtain your medicine depends on various factors, including:

Will you be able to take the medicine on your own, possibly with some education and guidance from a health care professional?

Examples of medicines that fall into this category include medicines taken by mouth and self-injectable medicines. These medicines will likely be delivered to you. Or you may be able to pick up these medicines at a local pharmacy.^{19,16,34,36}



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continued from page 6

Does the medicine need to be administered by a health care professional either at your home or at a health care facility? Examples of medicines that fit into this category include infusion medicines and certain types of injections. In these cases, the specialty pharmacy may deliver your medicine in one of the following ways³⁷:

- ▶ Send the medicine to your health care provider prior to your appointment.

- ▶ Send the medicine to you. In this case, you will be responsible for storing the medicine. Be sure to follow the storage instructions carefully.

The health care provider administering your medicine may also have its own specialty pharmacy. This pharmacy may dispense your prescribed medicine directly to your provider.³⁷

Pre-Treatment Testing

You may be required to undergo certain tests to help identify the right specialty medicine for you. For instance, individuals with cancer may need to get **biomarker testing** to identify certain

proteins, genes, and other molecules inside cancer cells. This information can help doctors determine the types of targeted treatments that would work best.³⁸



Treatment with Your Specialty Medicine

Once you have learned about your medicine, worked out the coverage details, and know how your medicine is going to be delivered, you are ready to start treatment. To help you understand what to expect, this journey is organized based on how you take your medicine.

Go to (or click on) the description that best describes how you will take your specialty medicine:



By mouth:
Go to
“Treatment:
Oral Medicines”
on page 8



By injection, or shot:
Go to
“Treatment:
Injectable Medicines”
on page 9



By inhalation:
Go to
“Treatment:
Inhaled Medicines”
on page 10



By infusion: Go to
“Treatment:
Intravenous (IV)
Infusion
Medicine”
on page 10

Remember: The specialty pharmacy will be in touch with you on a regular basis when you are on your specialty medicine.⁸ Be sure to reach out to your specialty pharmacist or health care provider with any questions or concerns.

Treatment: Oral Medicines

Medicines taken by mouth come in various forms, including tablets, capsules, and liquids. You swallow these specialty medicines just like other oral medicines.^{39,40}



Follow the instructions on the medicine label as well as any directions from your specialty pharmacist or doctor.⁴¹

Below are some **dos** and **don'ts** for oral medicines:

- ▶ **DO** take the medicine exactly as prescribed. Various tools are available to help you or your caregiver remember when to take the medicine, including pill boxes and reminder alarms.⁴²
- ▶ **DON'T** split or crush pills without first checking whether it's OK with your specialty pharmacist or doctor.⁴³
- ▶ **DON'T** stay silent if you are having trouble swallowing your pills or capsules. Ask your specialty pharmacist or health care provider about options. For instance, the medicine may be available in liquid form.⁴²



Treatment: Injectable Medicines (Given by Shot)

Types of injections



Subcutaneous:
the injection (shot) is given in the fatty tissue under the skin.⁴⁴



Intramuscular:
a shot of medicine is given into a muscle.⁴⁵

A growing number of injectable medicines can be administered by patients, or their caregivers, at home. These medicines are sometimes called “self-injectable drugs.”

However, other injectable medicines need to be administered by a nurse or other health care professional, either in your home or in a health care setting, such as in your doctor’s office or in another outpatient setting.⁴⁶⁻⁴⁸

Self-Injectable Medicines

Directions differ for self-injectable medicines. Some require the patient or caregiver to put the right amount of medicine in a syringe before giving the injection.^{44,45} Other self-injectable medicines

arrive pre-filled in various devices—such as pens, syringes, and auto-injectors—which can make it easier to manage.^{46,49}

You, or your caregiver, will be taught how to prepare and give your specific injection. It’s important to ask questions if you don’t understand.^{48,50}

Here are some **dos** and **don’ts** for self-injectable medicines:

- ▶ **DO** ask your health care provider for empty syringes or pens that you can use to practice giving yourself injections.⁵⁰
- ▶ **DO** use ice as pain relief. About a minute before you inject yourself, ice the injection site. Then clean the area with alcohol before injecting. You might also ask your doctor if numbing cream may help with pain.⁵⁰
- ▶ **DON’T** hide your anxieties. Tell your doctor or specialty pharmacist if you are nervous about giving yourself an injection. They may be able to suggest an alternative. Or they can help you overcome your fears.⁴⁸
- ▶ **DON’T** hold your breath when giving yourself injections. Instead take deep breaths, which can help you relax.⁴⁸

Professionally Administered Injections

If a health care provider will be giving you the injection(s), find out when and where you will get the treatment. The provider can also tell you what to expect during the procedure.



Treatment: Inhaled Medicines

Some specialty medicines are inhaled, or breathed into your lungs.⁵¹



Common devices for taking inhaled medicines include^{51,52}:

- ▶ **Soft mist inhalers**, which deliver a slow-moving mist of medicine⁵¹
- ▶ **Nebulizers**, which turn liquid medicine into mist that you breathe in⁵³
- ▶ **Dry powder inhalers**, which are devices that allow you to inhale powdered medicine⁵¹

Here are some **dos** and **don'ts** for inhaled medicines:

- ▶ **DO** get training on how to use your inhaler device. Using the device incorrectly may result in little to no medicine reaching your lungs. Your health care provider or specialty pharmacy can help you learn the correct way to use your inhaler device.⁵²
- ▶ **DON'T** forget to clean your inhaler regularly. Check instructions from the drugmaker to see how and how often you should clean it. This will help ensure the inhaler works well.⁵¹

Treatment: Intravenous (IV) Infusion Medicines

What is an IV infusion?

Some medicines are administered intravenously, which means that they are delivered into a vein. This allows the medicine or fluid to enter your bloodstream right away. IV medicines may be given directly into a vein or through a device called an IV line.⁵⁴



Some patients have IV access devices, called catheters and ports, which may make getting infusion treatments easier.⁵⁵

- ▶ **Catheters** are thin plastic tubes placed inside a vein. The infused medicine is then given through the catheter.⁵⁵
- ▶ **Ports (also called port-a-caths)** are devices placed under the skin by a surgeon or radiologist. The **port** is connected to a catheter. During an infusion, the needle is inserted through the skin into the port. Ports can stay under the skin for weeks, months, or years.^{4,55}

Both these devices can reduce how often patients have to have needles inserted into their veins for infusion treatments or to take a blood sample for testing.

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continued from page 10

Professionally Administered Infusions

Infusions are usually administered by health care professionals. An infusion can be done at the hospital, in your doctor's office, at an infusion center, or in your home.⁵⁶ Your doctor, specialty pharmacy, and/or infusion provider will educate you on what to expect before, during, and after your treatment(s).⁵⁷

Infusion treatment appointments can vary in length, from 30 minutes to a full day.⁵⁷ Many patients need to get lab tests before getting their infusion medicine. The infusion nurse may also check your height and weight, which helps determine how much medicine you need.⁵⁸ You may also be given some medicines before the infusion treatment to prevent or ease side effects.⁵⁷

After your infusion treatment is done, a nurse will explain what you should do if you experience any side effects, such as feeling tired or nauseous. You will also want to find out when your next infusion treatment is, if applicable.⁵⁸

Below are some **dos** and **don'ts** when getting infusions administered by a health care professional⁵⁷:

- ▶ **DO** drink a lot of water and other fluids before your appointment, unless your health care provider gives you different instructions.
- ▶ **DO** bring along a book, magazine, laptop, or other item(s) to help you pass the time during your treatment. The facility where you are getting your infusion may also have televisions and other entertainment. Alternatively, you could take a nap.
- ▶ **DO** arrange for someone to drive you home if the medicine you will be given may make you tired.
- ▶ **DON'T** keep questions or concerns to yourself. Instead, talk to your doctor, infusion nurse, or other health care professionals. For instance, if you are experiencing side effects, let the infusion nurses know. Then they can help you manage the side effects.

Self-Infused Medicines

Sometimes patients, or their caregivers, may be able to administer infusible medicines at home.¹⁰ If this is an option for you, talk to your doctor, specialty pharmacy, or home infusion provider about getting the training needed to administer the medicine. Your specialty pharmacy can arrange to have your medicine, as well as supplies and equipment (for example, an infusion pump, needles, syringes, dressings) sent to your home.⁹

A home care nurse will check on you regularly to see if the medicines are working. The nurse may also take your blood for any lab tests your doctor needs.⁵⁹

Here are some **dos** and **don'ts** for self-infused medicines⁵⁹:

- ▶ **DO** wash your hands before giving an infusion. This can help prevent infections.
- ▶ **DO** watch for signs of an adverse reaction to the medicine, such as shortness of breath or itching. Again, contact your health care provider. If it's an emergency, call 911
- ▶ **DO** keep a journal and note any questions or concerns you have. You might also note how you feel. You can then refer to this log when talking to your health care provider about your condition.
- ▶ **DON'T** ignore redness, swelling, or other signs of infection near the injection area. Symptoms of a widespread infection include body aches, fever, and feeling very tired. Contact your doctor, pharmacist, or nurse right away. If you suspect you have a life-threatening infection, call 911.



Monitoring

When your doctor was working to diagnose your condition and develop a treatment plan, he or she may have ordered various tests. These tests might have included^{60,61}:

- ▶ Lab tests to examine samples of tissue or bodily fluids such as blood or urine.
- ▶ Imaging studies (for example, X-rays, MRI, ultrasound) to look inside your body.

While you are taking your specialty medicine, you may need additional lab and imaging tests to see if the medicine is working or causing any side effects.^{60,61} In addition, your doctor may order blood tests to see whether the amount of the drug in your body is in the therapeutic range, or at an amount that is medically helpful and not dangerous.⁶²

Your specialty pharmacy will also be in regular contact with you. A pharmacist or nurse from the pharmacy will check how your therapy is going, answer any questions you have, and remind you to refill your prescription.⁶³



Remember, too, that you can ask your specialty pharmacist or nurse for help if you are having trouble taking your medicine as directed. They can help with a variety of issues, from addressing side effects or insurance issues to reducing hassles related to filling your medicine.²





Glossary:

Biologic products (also known as biologics): 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. Biologics can be made of sugars, proteins, or nucleic acids, or of complex combinations of these substances. Biologics may also be living entities, such as tissues and cells. Types of biologic drugs include vaccines, blood and blood components, allergens, gene therapy, tissues, and proteins.^{4,5}

Biomarker testing (also known as genomic testing or tumor testing): Examining proteins, genes, or other markers in cancer cells to help determine the best treatment.³⁸

Biosimilar: A biologic product that is highly similar and has no clinically meaningful difference to an existing approved biologic drug.²⁸

Deductible: The amount you must spend on covered medicines or health care services before your health plan begins to pay. For instance, if you have a \$2,000 deductible, you would have to pay the first \$2,000 of covered services yourself. After you pay your deductible, you usually pay only a copayment or coinsurance for covered medicines or services. Your health plan pays the rest.²⁷

Drug interactions: Drug interactions can increase or decrease the action of a medicine, leading to unwanted or dangerous side effects. There are three different types of drug interactions⁶⁴:

- ▶ Drug-drug interactions: Unwanted side effects, such as drowsiness, sometimes occur when two or more medicines are taken at the same time.
- ▶ Drug-food/beverage interactions: When a drug interacts with a food or drink to cause side effects.
- ▶ Drug-condition interactions: People with certain health conditions may have adverse reactions to some medicines.

Generic drug: Medicines that have the same active ingredient and are as safe and effective as an existing brand-name drug. These medicines usually cost less than the brand-name drug.²⁷

Out-of-pocket: The amount that you pay for health services and medicines that are not reimbursed by health insurance. These costs may include copayments, coinsurance, and deductibles.²⁷

Out-of-pocket limit: The most you have to pay for covered health care or medicines in a year. It may include deductibles, coinsurance, and copayments. Once the limit is reached, your health plan pays 100% of the costs.²⁷

Port (also called port-a-cath): A medical device placed under the skin to deliver medicine and other treatments as well as to take blood samples for testing. The port is connected to a thin, flexible tube (called a catheter) that is inserted into a vein. A needle is inserted through the skin into the port to give treatments or take blood.⁴

Prior authorization: When a health plan must issue an approval before a medicine or health service will be covered by the plan.²⁷

Step therapy: When health plans require members to try a lower-cost medicine(s) before providing coverage for a higher-cost medicine.²²



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