

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 features¹⁻⁶:

- ▶ 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.⁷ Check your health plan's **formulary** (drug list) to see what your plan considers a specialty medicine.

How do I take my specialty medicine?

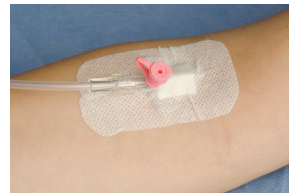
Specialty medicine can be taken in various ways⁶:



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^{1,2}:



Your home



Your doctor's office



A hospital



An outpatient facility (for example, an infusion center)



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What diseases do specialty medicines treat?

The number of specialty drugs grew from less than 30 in the early 1990s to 400 in 2017.⁸ New specialty medicines continue to be approved. About two-thirds of novel prescription medicines approved in 2019 were specialty drugs.⁹

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 by treatment with specialty drugs.^{10,11}

In addition, new medicines have been developed to treat serious rare diseases, such as sickle cell disease and hemophilia.^{3,12,13} In some cases, a specialty drug may be the only treatment available for a life-threatening disease.¹⁰

Examples of Diseases and Conditions Treated by Specialty Medicines^{3,10,11,13}:

▶ Asthma	▶ Infertility
▶ Atopic dermatitis	▶ Migraine
▶ Blood disorders, such as anemia, neutropenia, and thrombocytopenia	▶ Multiple sclerosis
▶ Cancer	▶ Organ transplant
▶ Crohn’s disease	▶ Osteoarthritis
▶ Cystic fibrosis	▶ Osteoporosis
▶ Gaucher disease	▶ Psoriasis
▶ Growth hormone deficiency	▶ Rheumatoid arthritis
▶ Hemophilia	▶ Sickle cell disease
▶ Hepatitis	▶ Ulcerative colitis
▶ HIV/AIDS	



How can specialty medicines help you?

Many specialty medicines are used to help manage chronic conditions over time.¹⁰ For instance, drugs used to treat rheumatoid arthritis aim to reduce inflammation and pain and prevent joint damage.¹⁴

Some specialty medicines can cure certain diseases. For example, new **antiviral** medicines treat hepatitis C, a type of liver disease. After eight to 12 weeks of treatment, about 90 percent of patients can be cured.¹⁵

New types of specialty medicines, called **gene therapies**, hold promise to treat or halt the progression of some diseases. Some gene therapies fix or add working copies of the faulty gene inside the cells of a patient's body.¹⁶ Other gene therapies enhance the immune system's ability to recognize and attack cells that are a threat.¹⁷ Currently, only a small number of gene therapies have been approved by the U.S. Food and Drug Administration (FDA). Many more are being tested, and experts predict many different gene therapies may be available in coming years.¹⁶

Why might I have to get testing before my doctor prescribes specialty medicine?

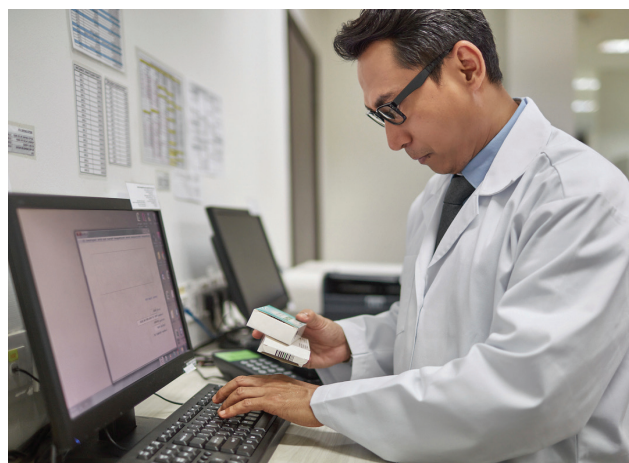
Before some specialty medicines are prescribed, certain tests may be required to



help determine the therapy most likely to result in a favorable response. For instance, **biomarker testing** can help patients with cancer and their doctors determine the right treatment. Some cancer treatments will only work on patients whose cancer cells contain certain proteins, genes, or other molecules.¹⁸

Where can I get my specialty medicine?

Many health plans require members to get specialty medicines filled by a specific specialty pharmacy.¹⁹ In some cases, your specialty pharmacy may ship your medicine directly to you or to your doctor. In other cases, you may be able to pick up your specialty medicine at a local retail or hospital pharmacy.^{19,20,21}



In addition to filling your prescription, specialty pharmacies provide services to support you before and during treatment, including¹:

- ▶ Helping you obtain insurance coverage for your medicine
- ▶ Training in how to use your medicine
- ▶ Providing ongoing monitoring and education
- ▶ Managing medicine dosing and side effects
- ▶ Coordinating your care with your doctor, your health plan and, in some cases, with the drugmaker²²



Why do specialty medicines cost more?

There are many reasons why specialty medicines may cost more than traditional medicines. These could include^{23,24}:

- ▶ They are often complicated to manufacture and administer.
- ▶ Handling and distributing these medicines can be complex and costly.

Your specialty medicine may be covered under your health plan’s pharmacy or medical benefit^{6,25}:

- ▶ If the medicine needs to be administered to you by a health care provider, it will likely be covered under your medical benefit.
- ▶ If you take or give the medicine yourself, it will likely be covered under your pharmacy benefit.

How much you pay **out-of-pocket** for specialty medicines will depend on your health plan’s coverage. Many plans place drugs into different “tiers” on their formularies (drug lists). Each plan can divide its tiers in different ways. (See table below.)

The **copayment** or **coinsurance** that you pay will differ, depending on the tier. Generally, a drug in a lower tier will cost you less than a drug in a higher tier.^{26,27}

Most health plans put costly drugs, such as specialty drugs, in the highest—and most costly—tiers of their formularies.²⁷ Some specialty medicines may have **generic** or **biosimilar** versions available:

- ▶ A generic drug has the same active ingredient as a brand-name drug.²⁸
- ▶ A biosimilar is a biologic product that is highly similar to an FDA-approved biologic product.²⁹

Generic and biosimilar versions may cost you less out-of-pocket than brand-name drugs.^{29,30,31}

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**.³²

Example of Formulary Tiers²⁷

Tier	What’s Covered	What You Pay
1	Most generic prescription drugs	Lowest copayment
2	Preferred brand-name prescription drugs	Medium copayment
3	Nonpreferred brand-name prescription drugs	High copayment
4	Specialty drugs	Highest copayment or coinsurance Generic specialty drugs, biosimilars, and preferred specialty drugs may have lower copayments or coinsurance ^{30,31}



What if I can't afford my specialty medicine?

If you need help paying for your medicine, you may be eligible for patient assistance programs. Some programs may ask that you meet medical or financial requirements. Most specialty pharmacies can connect you to these

programs, which are offered by drugmakers and other organizations.^{19,33}

You might also want to find assistance on your own. Below are some organizations that can help you get started.

If you don't qualify for assistance, ask your doctor if there is a similar medicine covered by your health plan that costs less.³⁴

NeedyMeds

needyeds.org/pap

Website with free information on programs that may help people who can't afford medicines and health care costs.

E-mail: info@needyeds.org

Phone: 1-800-503-6897

Medicine Assistance Tool

medicineassistancetool.org

Patients can search for potential financial assistance programs.

Phone: 571-350-8643

RxAssist

rxassist.org/patients

Resource center with an online database where you can search for patient assistance programs by drug name.

E-mail: info@rxassist.org





Glossary:

Antiviral: Prescription medicines that fight viruses in your body.³⁵

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.¹⁸

Biosimilar: A biologic product that is highly similar and has no clinically meaningful difference to an existing approved biologic drug.²⁹

Coinsurance: The percentage of the cost of a covered drug or health care service that you must pay. For instance, if a covered medicine costs \$100 and you owe 20% coinsurance, then you would need to pay \$20 and your health plan would pay \$80.²⁸

Copayment: A fixed dollar amount you must pay for a covered medicine or health care service.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.²⁸

Formulary: A list of drugs covered by your health plan.²⁸ Most health plans place drugs into different “tiers” on their formularies with each tier costing a different amount. Generally, a drug in a lower tier will cost you less than a drug in a higher tier.²⁷

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.²⁸

Gene therapy: According to the American Society of Gene + Cell Therapy, “Gene therapy is the introduction, removal or change in genetic material—specifically DNA or RNA—into the cells of a patient to treat a specific disease.”¹⁶

Infusion: When medication or fluids are administered through a needle, usually into a vein (intravenous infusion).³⁶

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.²⁸

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.²⁸



Notes

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