

What's So Special About Specialty Pharmacy?

A USER'S GUIDE TO SPECIALTY PHARMACIES



Glossary of terms

Brand-name drug: A drug marketed under a specific trade name by a drug manufacturer. These drugs are still under patent protection, making the original manufacturer the only company able to make this medication.

Co-insurance: The percentage of the negotiated cost of your prescription drug that you pay after you have finished paying your deductible. Your health plan pays the rest.

Complex chronic condition: A chronic condition that requires you to take a specialty medication. Examples are medications used to treat cancer, chronic inflammatory conditions, Cystic Fibrosis, Hepatitis C, HIV, post-transplantation.

Co-pay/Co-payment: The dollar amount you pay for your prescriptions after you have finished paying your deductible.

Deductible: The amount you pay for prescriptions before your health plan begins to pay.

Drug tiers: Tiers are coverage levels, often having different out-of-pocket costs.

Exclusion/Off-formulary: A drug, product, or service that is not covered by your plan.

Formulary/Preferred drug list: A list of medications preferred by your insurance and prescription benefit plan.

Generic drug: A drug with the same active ingredient as the brand-name drug, which the FDA has deemed equally safe and effective. Generic drugs usually cost less than brand-name drugs.

Pharmacy benefits manager: A third party administrator that delivers, monitors, and manages prescription drug benefits on behalf of your employer and/or health plan.

Specialty medications: Drugs taken for complex chronic conditions. These drugs are often injected, given through an IV, or taken by mouth. These drugs can cost more and require additional clinical monitoring. They may not be available at retail pharmacies.

Specialty pharmacy: A type of pharmacy that dispenses specialty medications. Specialty pharmacies offer in-depth patient support such as clinical patient management and patient co-pay assistance programs to offset expensive co-pays of specialty medications.



One of the many ways medical providers treat patients is by using medications. But the way our health plans cover medications is not always crystal clear, especially if your doctor is treating you with a medication that must come from a specialty pharmacy. Because of the high cost related to research and development, specialty medications are more expensive than the ones you receive at your normal pharmacy. We hope to demystify the process of obtaining medications and help you understand the role of a specialty pharmacy in the process.

Types of pharmacies



RETAIL

A pharmacy where drugs are stocked and sold to patients who arrive at the store to pick up. These are the most traditional type of pharmacy locations that you commonly see around town. These can be local, independent pharmacies or large nationwide chains.



MAIL ORDER

A pharmacy that delivers medications to patients through the mail directly to their homes, rather than requiring patients to show up to a store to pick up their medications. Everything is done over the phone or online regarding your medications.



SPECIALTY

These pharmacies are advanced and work with medications that often have unique requirements or need special handling by the pharmacist (and the patient). Specialty pharmacies may deliver medications to you by retail or mail order. Specialty medications are administered to patients with complex, chronic conditions.

A specialty pharmacy manages rare, chronic, and often complex medical conditions that require an increased level of patient management. Typically, specialty pharmacies dispense high-cost, limited distribution medications for which patients may require financial assistance, specific dosing guidance, and counseling. The services provided by specialty pharmacies typically go beyond that of other pharmacies and are therefore likely to be more involved in your care. Generally, these pharmacies take care of prescriptions from start to finish,

monitor how you are managing your diagnosis and taking your medication, communicate with you or your caregiver often, and keep in touch with your doctor to make sure things are going smoothly. Specialty pharmacies also communicate with the patient's multidisciplinary healthcare team, handle shipping coordination, assist with enrollment in patient assistance programs and financial assistance, and deliver patient education and medication adverse effect counseling.



Answering your biggest questions

Why do medications have to be sent from a specialty pharmacy?

Often, specialty medications require special dosage, handling, administration, or storage. They may need to be injected or infused into a vein through an IV and given at a hospital or your doctor's office instead of at home. These specialty medications also generally require special follow-up care from a healthcare professional when you are taking them.

The medications that are most often dispensed from specialty pharmacies are not as commonly stocked in a retail pharmacy. These medications are used to treat complex, chronic, and/or rare conditions like cancer, HIV/AIDS, multiple sclerosis, or rare genetic disorders.

Because the medications dispensed at specialty pharmacies can be expensive, most of the pharmacies have departments dedicated to helping patients find financial assistance to pay for them.

Do I get to pick which specialty pharmacy I want to use?

Normally, once you are prescribed a specialty medication, you will be required to use a specialty pharmacy that is chosen for you. Most often, the insurance company will choose an in-network specialty pharmacy. However, sometimes it is up to the manufacturer of your medication that chooses only a small network of pharmacies in which to distribute their medication. If they have fewer pharmacies dispensing their medication, it allows the manufacturers to ensure their medication is being distributed carefully and securely.

How does my insurance pay for these medications?

One of the biggest healthcare barriers patients face can be navigating the details of their prescription drug coverage options. The more you know about and understand how your prescription drug coverage works, the better prepared you will be to take control of your health.

Within your health plan's prescription benefits, there are criteria often put in place to limit certain medications, like those that are new or expensive (which can be specialty medications). Specialty pharmacies help to navigate the insurance barriers you may face with these medications.

What is a drug formulary, or a preferred drug list?

A drug formulary, also called a preferred drug list (PDL), is the official listing of medications covered by your health plan. This formulary includes common drugs used to treat most health conditions. These medications are chosen by a committee, often called a pharmacy and therapeutics (P&T) committee, made up of doctors and pharmacists from various medical specialties and backgrounds. This committee reviews medications based on factors like how effective the medications are, their safety, and their cost.

The formulary should be organized in a way that shows members what is covered and how it's covered. The process is supposed to save money for you and your insurer, but it can feel like a hassle if you don't have all the facts.

Health plans review this list annually at a minimum, although the formulary can change at any time, even in the middle of a plan year. The P&T committee will generally make changes to the formulary when new medications come to the market or if the FDA (US government agency that regulates drug testing, labeling, and safety) decides that a previously approved medication is no longer safe or changes the way a medication can be used.

Any medication that is not listed on your medication formulary is considered non-covered and your health plan will most likely not pay for the medication. It is important to choose drugs that are on your plan's formulary because they will be cheaper and more cost-effective for your insurance company. You will probably be charged the full retail price for medications that are not on your health plan's formulary unless there is an option with your insurance for your doctor to appeal.

Most health plans contract with a third-party company to administer their drug formulary. This third-party is called a pharmacy benefit manager, often shortened to PBM. These PBMs assist health plans by working with drug manufacturers, wholesalers, and pharmacies. They help save insurance companies (and members) money by negotiating the prices of medication with pharmaceutical manufacturers. They also help manage utilization management programs, which are practices put in place to keep you safe by helping to make sure the medicines you take as prescribed by your doctor are used correctly.

Medications in the formulary/PDL will have coverage requirements or limits before insurance covers them. Some of the practices include prior authorization, supply limits/quantity limits, and step therapy.



Your health plan may decide to exclude a drug from the formulary for several reasons.

- 1 The US Food and Drug Administration (FDA) has not approved the medication for that particular health condition.
- 2 The medication is available over the counter.
- 3 The drug is used primarily for cosmetic or non-medical purposes.
- 4 The committee picked a medication of the same type that they found to be adequate and cost-effective to treat your condition.

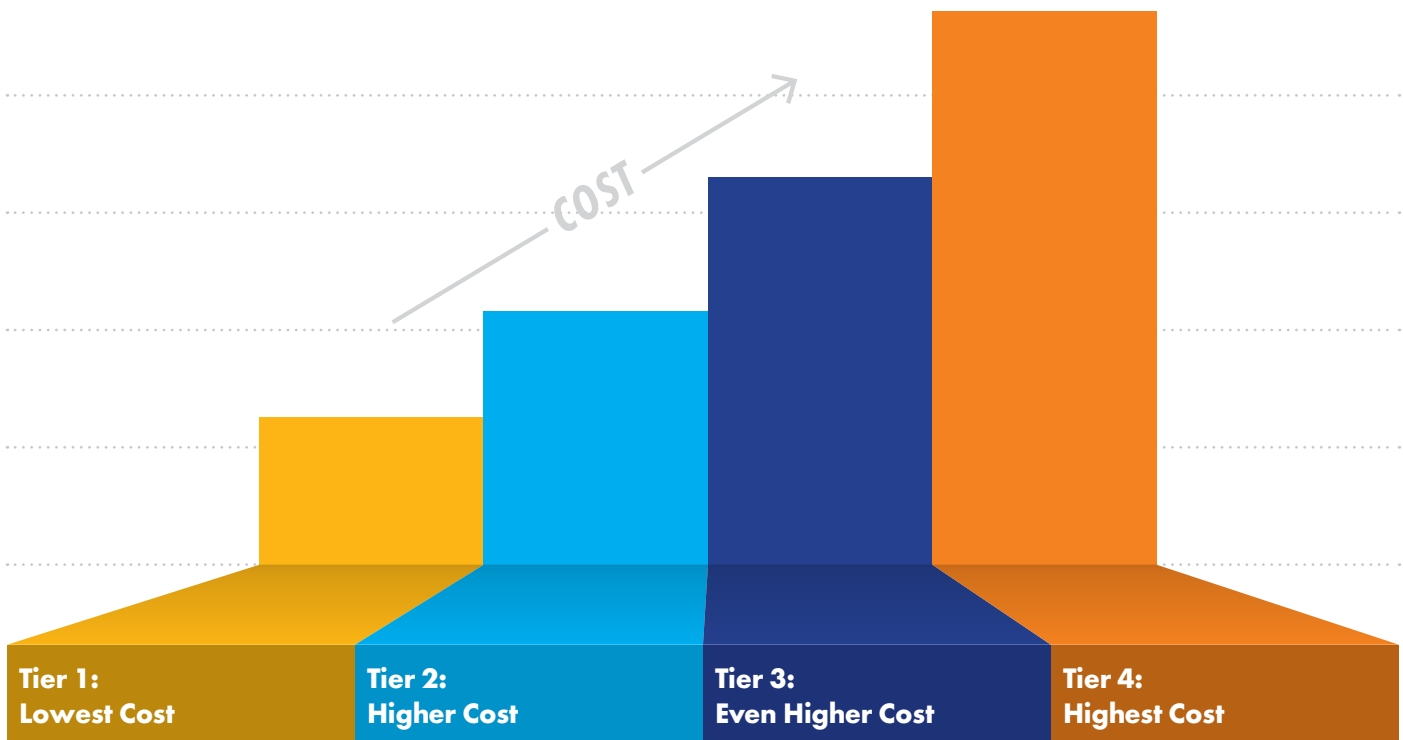
| Term | Definition | Why is this requirement needed? |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Prior authorization | A restriction placed on certain drugs that require your doctor to get approval from your benefit plan before your plan will cover the medication. The doctor must provide information on why you are taking the prescribed medication. Frequently noted as "PA" on the formulary. | Health plans often use prior authorizations to ensure that medications are being used and prescribed the right way. |
| Supply limits/ Quantity limits | A coverage limit on how often or how much of a medication you can have filled in a certain period or timeframe. Prior authorization can be completed by your doctor to cover the entire quantity. Frequently noted as "QL" on the formulary. | Health plans use supply/quantity limits to control costs as well as make sure you are safely taking your medications. |
| Step therapy | A requirement placed for you to try one or more alternative and often more cost-effective medications that also work for your diagnosis. Prior authorization can be completed by your doctor before the medication you are requesting may be covered. The prior authorization must provide that the alternative is not effective or causes unwanted side effects, before 'stepping up' to the medication your doctor prescribed. Seen as "ST" on the formulary. | Health plans utilize step therapy to ensure their members get the safest, most effective medication at an affordable price. |

How does the formulary/preferred drug list connect to what I pay for medications?

Drug tiers are the way health plans communicate to patients how much a specific prescription drug will cost. Tiers are the categories or levels that covered drugs are sorted into, usually presented in order from lower to higher costs. The part that can be confusing is that drug tiers are not standardized across insurance companies, and even plans offered by one company are not guaranteed to be the same. The number of tiers can vary by plan. Additionally, not all plans will place

the same drugs in the same tiers. However, all plans agree that the medications on a formulary must meet FDA safety standards.

Generally, formularies are three to four tiers. The medications on the lower tiers are cheapest, and as the tiers go up, so does the price. Below is an example of how a drug formulary may be structured.



Tier 1 holds the cheapest prescription drugs available to you, typically limited to generic drugs. Generic drugs are just as safe as brand-name drugs. The only difference between the two is the name and the cost savings. Some plans include cheaper brand-name drugs under Tier 1.

More expensive generic drugs and preferred brand-name drugs occupy this tier. If you must take a brand-name drug, try to work with your doctor to choose an appropriate one from Tier 2, as they are the most affordable.

Non-preferred and expensive brand-name drugs are typically in this tier. Your plan may include drugs in this tier that are new to the market. Most often, these drugs will leave a significant out-of-pocket cost to the patient.

This is the most expensive tier, usually occupied by brand-name and specialty drugs. These drugs typically do not have specific copays; instead, you'll pay a percentage of the total cost negotiated between the health plan and the manufacturer of the medication.



You and your doctor can check your plan's formulary/PDL to select medications covered under your insurance plan. Armed with this information, you and your doctor can choose the best course of treatment together. You can even find out from the formulary/PDL if a medication is deemed "specialty" and if additional information is needed from the doctor's office to obtain coverage.

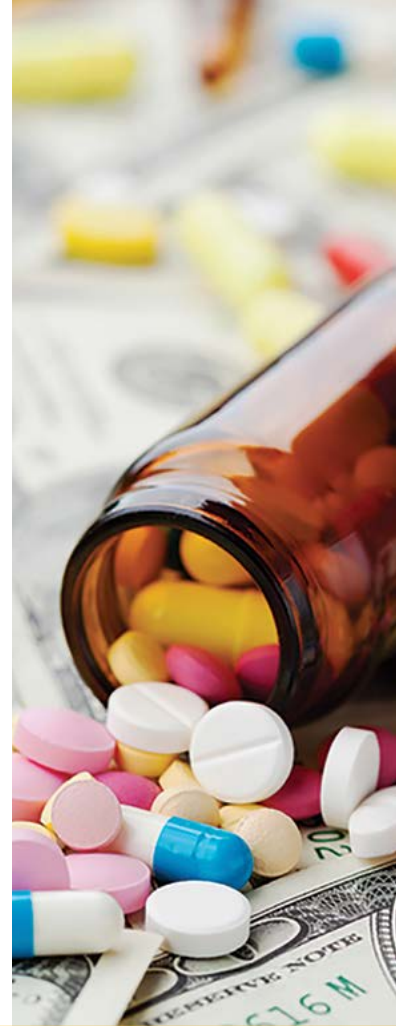
What if I don't agree with the tier my medication is placed on?

If you were prescribed a medication that is on a high tier and is not affordable for you, you or your doctor can request a tier exception override from your health plan. This would mean you could get a high-tier drug at a lower cost. First things first, get your doctor involved. If the medication requires prior authorization, your doctor's office will need to submit this before the tier exception can be filed.

Once you have permission to complete a tier exception override from the health plan, the next thing to do is to contact your doctor's office to let them know you will need help with a supporting statement. The supporting statement should explain why the preferred medication(s) (on lower tiers) are ineffective and/or harmful to you. There will be forms that need to be filled out, so be sure to call your health plan so they can direct you or send the correct form for your doctor to complete.

Once filed, you should hear back within 72 hours on a tier exception request. If approved, your medication will be covered with the lower tier copay. You can request a fast (expedited) appeal if your doctor feels your health condition could be seriously harmed. If your health plan grants an expedited process, you will get a decision within 24 hours.

Specialty medications are often not eligible for tier exception overrides. If your specialty medication has a high copay, confirm with your specialty pharmacist or health plan if a tier exception override can even be conducted; this will prevent unnecessary paperwork for you and your doctor. If a specialty medication is not eligible for tier exception override, there may be an option to enroll in a patient co-pay assistance program.



What do I do if the medication I need is not covered by my health plan?

Finding out that your prescription is not covered by your insurance plan or pharmacy does not mean that you will have to go without it. It means that there might be more paperwork needed to show that medication is necessary for your care. We discussed in the previous sections that prior authorizations, supply limits, and step therapy are examples of why your medication isn't initially being covered by your health plan.

Therefore, you must first determine why your medication is being denied. Your insurance may provide the pharmacist with a specific reason why your medication claim is not being covered. Having this information will help you decide on your next step. The denial reason from the insurance will tell you if you are missing information from your doctor, if the prescribed drug is not on your health plan's formulary, etc. If your pharmacist is not able to provide the reason, call your insurance company directly.

Even if your insurance denies your medication after troubleshooting any of the denial reasons listed (e.g. prior authorization), your next step can be to submit an appeal to your insurance to ask for reconsideration. Let your doctor know right away because it takes time to gather additional documentation and coordinate with your health plan for coverage. There may be an alternate medication for your condition that is covered and can be substituted.

Specialty pharmacies have a department or team that works to help patients get access to medications. Specialty pharmacies can facilitate prior authorizations between the health plan and doctor's office as well as provide primary and secondary literature to support the doctor's appeal. When calling a specialty pharmacy, ask to speak to a pharmacist or a billing specialist; these team members are trained and well versed in the specialty billing process.

Common medication denial reasons

- 1 The medication requires prior authorization.
- 2 The medication requires step therapy that has not been completed.
- 3 The medication is off-formulary or is excluded according to your health plan's benefits.
- 4 The maximum number of refills (or quantity) has been exceeded for this prescription.
- 5 Your health plan may only cover generic medications.



How can I maintain open communication with my pharmacist?

Pharmacists are a valuable resource for patients in many ways. They are well educated in both prescription and over-the-counter products and can help with any medication questions or concerns. Pharmacists work closely with your doctor to give you professional guidance about your health. Below are some things you can do to keep up good communication with your pharmacist.

1

Be sure to remain organized. Let your pharmacist know when you get new insurance or any of your insurance information changes. Make sure that the pharmacy has your most current insurance information on file or they may be processing your claim incorrectly, causing it to be rejected.

2

Make sure you understand how you will receive your medication. Sometimes the prescription will be delivered to you, and sometimes it will go to your doctor's office. If it's coming to you, make sure you know which courier will be delivering it and if you need to sign for the package. This will ensure you can plan to be home for delivery or if there is anything you need to do to handle the package when it arrives (such as refrigeration).

3

Don't be afraid to ask questions. If you don't feel comfortable with the medication and instructions (e.g. if you have to give yourself an injection), you may want to seek some help from your pharmacist about how to use and store the medication.

4

Be honest. Let your pharmacist know if there is anything that could impact your use of the medication; for example, trouble swallowing pills, struggling to read labels, remembering to take your medications, or are experiencing a medication side effect.

What do I do if I can't afford my specialty medications?

Specialty medications are expensive, and specialty pharmacies are knowledgeable about copay assistance programs tailored to patients and their respective health plans. Specialty pharmacists and billing specialists can help patients get access to medications through financial copay assistance. Here are some of the options they may explore with you:

Manufacturer's copay cards: Medication manufacturers frequently offer discount or coupon cards to eligible patients. These cards can lower your copay for your medication to a much more affordable rate, sometimes as low as \$5 a month.



Double-check with your specialty pharmacy if you and your prescription are eligible for manufacturer's copay cards. Copay card approval is on the spot.

Copay assistance organizations: These programs provide direct financial support to underinsured patients, even if you have government-sponsored insurance like Medicare, Medicaid, or Tricare. These programs require you to complete an application to determine if you medically and financially qualify based on individual program requirements. If approved, the program can help with your out-of-pocket costs including co-payments, co-insurance, and deductibles related to medication expenses. The programs typically have a cap on the grant amount you will receive, which will be communicated to you when you complete the application.



This is where you can ask for help from specialty pharmacists and billing specialists. They have the tools to find the correct national or local organization that can assist you with your specialty medication copays. The turnaround time for copay assistance approval from organizations is between minutes up to 1-2 business days.

Manufacturer's low cost/Free drug programs: If you are not eligible for a manufacturer's or organization's copay assistance program, are uninsured, or your health plan will not cover your medication, you may want to look into a medication program sponsored by the maker of the medication. Many manufacturers offer free drug programs or low-cost options specifically for those without insurance. Many of these programs have applications that require you to verify your income. If approved, the manufacturer will mail the medication to you or your doctor's office for your use.



Your specialty pharmacist and billing specialist can assist with the application process and follow-up calls with the manufacturer to make sure your forms are being reviewed promptly. The turnaround time for manufacturer's drug programs can take up to 1-2 weeks depending on how soon you can complete the paperwork and how long the manufacturer's approval checks and processes are.

Speak with prescribing doctor about alternatives: If your health plan will not cover the prescribed medication, talk with your doctor about what other options might be out there. There could be another, cheaper medication on your plan's formulary that works just as well that your plan will cover. Additionally, you may be eligible for clinical trials based on your health condition.

I was prescribed a medication that requires filling



at a specialty pharmacy. NOW WHAT?



3 Specialty pharmacist or billing specialist facilitates **prior authorization** with your doctor's office



Depending on your eligibility, the specialty pharmacist or billing specialist can assist in signing you up for a **manufacturer's copay card**, **organization's copay assistance program**, or **manufacturer's low-cost/free drug program**. If you are signed up for a manufacturer's low-cost/free drug program, you will receive your medication straight from the company

5

The manufacturer's or organization's copay assistance program is approved. Your copay is **reduced to \$5/month**



6

8




Medication is shipped to your house or doctor's office for administration

Still have questions about Specialty Pharmacies?

We're here to help.

 patientadvocate.org

 (800) 532-5274

421 Butler Farm Road | Hampton, VA 23666
800.532.5274 | patientadvocate.org

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