



Neuropathy
Action →
Foundation
Awareness • Education • Empowerment

Getting the Medications and Treatments You Need

Understanding Your Rights in California

As you search for a health insurance plan or coverage for your prescription medications, it is important to understand that insurance companies no longer pay for any and all drugs at any time you need them. Instead, they offer a number of different coverage options all with their own obstacles to navigate; some even have rules that may require you to pay more for the drugs that are actually best for you. (Your insurance company will give you an “Evidence of Coverage” document that explains the rules that apply to you.)



This brochure, developed by the Neuropathy Action Foundation (NAF), contains answers to general questions regarding how prescription drug insurance works and the rights patients have to access necessary medications. It also contains sample letters and useful contacts to help you advocate for and receive the services you are entitled to.

Needing Urgent Help

If your dispute with your insurance company involves a serious threat to your health, make sure you take prompt action. Most insurance companies offer expedited review for such cases. On page 5 of this document you will find some contacts to use when seeking help, including the phone numbers of applicable insurance plan regulators. If you need urgent help, make sure you say so up front.

Types of Coverage

If my doctor prescribes a drug for me, does my insurance company have to pay for it?

No. With respect to drugs, the four major types of health insurance policies provide:

- **No coverage** for any medications, but access to discounts that the company gets with selected pharmacies.
- **Generic-only coverage** that pays for most of the generic drug, assuming one exists, that is close enough to the brand name drug your doctor prescribed for you. If you need a brand name drug, you can get the same discounts as discussed above.
- **Formulary coverage** that pays for drugs on the list created by the insurance company. Drugs not on the list are not covered, but many states, including California, provide you with the right to appeal for non-covered drugs for medical reasons.
- **Preferred drug systems** that pay different amounts for drugs, depending on whether, and how much, they are “preferred” or “recommended” by the insurance company. This is known as “tiered co-payments” or “preferred drug levels.” Patients who need drugs that are not “preferred” have higher out-of-pocket costs with these plans.

Brand Name vs. Generic Drugs and Substitutions

What are brand name drugs?

Brand name drugs are the drugs sold by the manufacturer that, after years of research and clinical trials, developed them. Depending on how long the drugs have been on the market, they may no longer be protected by patent laws, which provide the right to be the only drug with the same active ingredients. Once the patent ends, generic drugs, which try to copy brand name ones, may be sold to patients.

Why is there a push toward generic drugs?

They are usually cheaper than brand name drugs, which is why insurance companies prefer them. Insurance companies promote the prescription of generic drugs by: 1) only covering them and not covering brand name drugs; 2) requiring that you pay higher copayments for brand name drugs; and 3) offering physicians a financial bonus if they meet a target generic prescribing rate.

I understand that generic drugs are cheaper, but are they the same as brand name drugs?

According to the federal Food and Drug Administration (FDA), a generic drug must have the same amount of the active ingredient of the brand name drug, but may differ in other respects, such as the way the drug is released into your system or the addition of fillers such as flavors and preservatives. Further, while the FDA approves generic drugs to assure they can be used in place of brand name ones, its standards do not require that the generic be exactly the same. This is most important in the area of “bioequivalency”—the rate and way the drug is absorbed by the body. The FDA allows a difference of up to 20% from the brand name drug.¹

¹ See U.S. Food and Drug Administration, Approved Drug Products with Therapeutic Equivalence Evaluations, (28th Ed. 2008).

Are generic drugs as good for me as brand name drugs?

They can be, but it is not always the case. Because of the differences between the brand name drug and its generic counterpart, there may be a medical reason why the generic version would not be as good for you.

Can the drug my physician recommends get substituted by another drug, such as a generic one?

Yes, it can. In California, pharmacies generally can make this switch only if the physician has not indicated that the prescription must be filled as written.² However, patients must be informed of the change.³

Therapeutic substitution, on the other hand, occurs where less expensive drugs that are not chemically equivalent are substituted. Generally speaking, most states do not allow pharmacies to engage in this activity. It usually occurs where the prescribing physician is encouraged, through bonus pay or other incentives, to make the switch. As long as the decision to make the change is the prescriber's, this activity is usually legal, though many states, such as California, do prohibit financial incentives from influencing a treatment decision.⁴

Drug Lists

How can I get a copy of my insurance company's formulary or preferred drug list?

The best way to get a current copy of your insurance company's drug list is to go to the company's website. If you are already a member, you can also call your company's member services department. (The phone number is usually on your insurance identification card.) For Medicare plans, you can use the Medicare Prescription Drug Plan or Formulary Finder tool at www.medicare.gov, or call the Medicare helpline at (800) MEDICARE, or (800) 633-4227, and ask a customer representative to let you know what drugs are covered and also compare plans.

What if I am comparing plans and want to see the insurance company's different drugs lists?

Most companies are required by law to provide you with a list of drugs that are covered by each of their insurance products. This information can usually be accessed on the company's website or by calling its member services department. If it doesn't, use the **Help Form** on page 8 of this document and the NAF will help you.

² See Business and Professions Code Section 4073(b).

³ See Business and Professions Code Section 4073(e).

⁴ See Health & Safety Code Section 1348.6.

If the drug I need is on the list, does that always mean the insurance company will pay for some of it?

Not necessarily. Again, insurance companies offer many different types of products that cover and exclude different drugs. Many drug lists explain that just because a drug is on the list does not mean that your policy will pay for it. So the best approach is to contact your employer's benefits manager, if you are getting your insurance through your employer, or the insurance company's member services department to be sure you understand which drugs are covered under your plan.

Changing or "Switching" Drugs on the List

Can my insurance company take drugs off the formulary or preferred drug list?

Yes, it can. Many insurers—even Medicare plans—do this.

What are my rights if I was covered for a drug and then the drug was removed from the list?

In California, it depends upon if your insurance company is regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). The DMHC regulates HMOs and some Blue Cross and Blue Shield PPOs. The CDI regulates PPOs, including some offered by Blue Cross and Blue Shield.

If you are in a plan regulated by the DMHC, then you are protected from drug switches. The law provides that such plans may not limit or exclude coverage for a drug for an enrollee if:

- The drug was previously approved for coverage for the enrollee's medical condition;
- The patient's doctor continues to prescribe that drug for the enrollee; and
- The drug is appropriately prescribed and considered safe and effective for treating that condition.⁵

In this case, you are protected by the continuity of care law. If your plan tries to switch drugs, you can protest with a letter. (See **Model Letter 1** on page 6.)

If you are in a plan regulated by the CDI, then you have no similar protection, although if the drug gets removed from the formulary, plans should give you the right to appeal for medical necessity reasons. However, if a drug is switched to a more expensive tier, the cost of the drug may be too expensive. In that case, the switch could mean that, from a practical standpoint, you cannot get your drugs. If this

⁵ See Health & Safety Code Section 1367.22.

happens, please use the **Help Form** on page 8 to let the NAF know. We may be able to help you.

With respect to Medicare Part D plans, there is no similar continuity of care law, but there are some useful protections. For example, prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a plan must, among other things:

- Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or
- At the time an affected enrollee requests a refill of the Part D drug, provide the enrollee with a 60-day supply of the Part D drug under the same terms as previously allowed, and provide written notice of the formulary change.⁶

Further, where there has been a drug switch in a Medicare plan, enrollees may seek an “exception,” discussed below, to obtain the needed drug.

Costs

What types of out-of-pocket expenses will I likely have when getting my medications, assuming the drugs are “covered”?

Assuming your insurance company covers the drug (remember, if it doesn’t, you are responsible to pay for the entire cost), there are three areas that you need to be aware of that will impact how much you will need to pay:

- **Annual benefit maximum.** Some insurance plans will only pay up to a certain dollar amount each year for your drugs. This amount differs from plan to plan. It is important to understand that once this amount is reached, the plan will no longer help you pay for your drugs during that year, and any unused amount will not be carried forward to the next year.
- **Deductible.** This is the amount you must pay for your drugs before your insurance company will help pay for any of them. For example, if your plan has a pharmacy deductible of \$750, you will need to spend \$750 on drugs before the plan begins covering the cost of your drugs, minus your copayment. These deductibles are usually in addition to the deductible you have for your general healthcare expenses. Often, these deductibles apply only if you use brand name drugs.
- **Copayments.** This is the amount you need to pay each time you receive your medication. Again, plans

have different rules and the copayment can be a flat dollar amount or it can be a percentage of the cost of the drug. Further, in preferred drug systems, the copayment increases depending on what “tier” (level of preference) your drug is placed in. The higher the “tier,” the more you will need to pay, especially if you need a non-preferred, brand name drug.

My plan limits my out-of-pocket expenses. Do my drug costs count toward that limit?

Usually not. Again, you should know the rules of your plan.

Limitations and Prior Approval

Other than costs, what types of rules can my insurer impose before I can get my drugs?

There are a number of things insurance companies do to help reduce their costs and/or control your medications. These can include:

- **Prior authorization.** Certain drugs, even those on your insurance company’s drug list, require your insurer’s approval before it will agree to help pay for them. If that is the case, your doctor will need to explain to the insurer why the drug is medically necessary for you. While most doctors find it difficult to do “battle” with insurance companies, it is important for you to work with your doctor to make sure that he or she advocates on your behalf. This process may take time, so you may need to pay the entire cost of the drug until a decision is made.
- **Step-therapy.** Some insurers may require that you try certain less expensive drugs before they will cover the one your doctor initially recommended. If, however, it is medically necessary for you to use the “first-line” drug before trying the cheaper alternatives, again, your physician should be able to get a medical exception for you from the plan. If you are not given the exception, we urge you to contact the NAF so that we can help you. You can either call us or use the **Help Form** on page 8.
- **Quantity restrictions.** Most insurers set quantity limits on some of the drugs they will help pay for. Again, if your doctor believes that you need more medications than the limit, the plan should have a process in place to allow your doctor to ask for a medical exception. Note, under California law, DMHC plans may limit the amount of the drug dispensed at any one time to a 30-day supply or, if the treatment is less than 30 days, for the medically necessary amount of the drugs.⁷

⁶ 42 C.F.R. Section 423.120.

⁷ 28 CCR 1300.67.24.

Maintenance drugs may be dispensed in a supply of 2 months or greater.

- **Mail order.** Some plans may require that you use their preferred mail order pharmacies in order to get your drugs. DMHC plans may establish a mandatory mail order process for maintenance drugs when dispensed in a 3-month supply or greater. No additional fees shall be imposed on the enrollee.⁸
- **Off-label.** Some plans may deny coverage if the drug has not been specifically approved by the FDA to treat your condition. Many states recognize the medical need for patients to receive drugs under these circumstances. For example, in California, insurers may not limit or exclude coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA, provided that all of the following conditions have been met:
 - The drug is approved by the FDA.
 - The drug is prescribed by a participating licensed healthcare professional for the treatment of a life-threatening condition; or
 - The drug is prescribed by a participating licensed healthcare professional for the treatment of a chronic and seriously debilitating condition, medically necessary to treat that condition and on the plan formulary.
 - The drug has been recognized for treatment of that condition by one of the following:
 - The American Medical Association Drug Evaluations.
 - The American Hospital Formulary Service Drug Information.
 - The United States Pharmacopoeia Dispensing Information, Volume 1, “Drug Information for the Health Care Professional.”
 - Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.⁹

Appeals

What can I do if I cannot get my medication because my medication is not on the drug list, is in too expensive a “tier” or there is some other rule that prevents me from getting it?

There are a number of things that you can do:

- **Prior authorization and request for medical exemption.** First, all that may be needed is for your doctor to fill out a request for either prior authorization or medical exemption. These forms are generally on the plan’s website and can be easily accessed. Your doctor will need to provide specific information about your case and explain why you need a certain drug.
- **Ask your employer for help.** You may wish to seek the help of your employee benefits manager or whoever else in your company works with your health plan in securing coverage. Many employers have worked with plans to reduce or eliminate copayments to “take not the cheapest medications, but the ones they need the most.”¹⁰ Purchasers of health coverage are increasingly realizing that getting the right care early on saves money in the long run.
- **Appeal.** First, if the best drug for your condition is placed in a tier that is too expensive for you, or there are other hurdles you need to go through before you can get it, you may be able to appeal to have this drug placed in a lower, less-expensive tier or have the restriction removed. Medicare Part D plans allow you to do this. Some plans will also allow you to do this under their general appeals process for medical necessity denials, even if it is not explicitly stated in their rules.

In California, you have the right to appeal to get a non-formulary drug if the plan is regulated by the DMHC. CDI plans also should provide you with a right to appeal decisions that prevent you from accessing your drugs so long as there is a drug benefit, under the general appeals process. If they do not, use the **Help Form** on page 8.

With respect to Medicare Part D plans, an easy process has been set up for enrollees and/or their physicians. It is called the “exception process.” Enrollees can use this process for virtually any plan decision that restricts access to necessary drugs, such as requests for non-formulary drugs, requests for lower copayments and requests to be relieved from quantity limits.

⁸ 28 CCR 1300.67.24.

⁹ Health & Safety Code 1367.21, Insurance Code 10123.195.

¹⁰ See *New Tack on Copays: Cutting Them*, Wall Street Journal, May 8, 2007.

Regardless of whether your coverage is with Medicare or a private insurance company, you need to make sure that the matter is appealed; while your doctor should help you with this, you need to take charge of the appeal and be sure to present facts. Your physician may be able to help you get to sources of medical information that will support your appeal. You can use **Model Letter 2** on page 7 as a guide.

Blood Plasma Protein Therapies

Many of the same premises described in this brochure also apply to blood plasma protein therapies, including immuno globulins such as IVIG, blood clotting factors and alpha 1 proteinase inhibitors. However, please keep in mind there are no generic versions of blood plasma protein therapies. Many insurers will cover each brand of therapy (including Medicare and Medicaid) but some insurers may require prior authorization or step-therapy.

Each brand of a blood plasma therapy is therapeutically different, thus, it is not a “one size fits all” approach. For example, different brands of IVIG have different indications and vary clinically. Therefore, you should work with your physician and insurer, if necessary, to ensure coverage of the brand of therapy that works best for you.

In addition to the therapy that works best, the same holds true for site of service. Many insurers may place restrictions on where your therapy may be administered. You may need to work with your physician and insurer to ensure your therapy is administered in the most clinically appropriate site of service regarding your individual care.

Lastly, you will need to determine where the better coverage benefits reside, either under the insurance plan’s major medical benefit or the pharmacy benefit. These two coverage benefits do not communicate across the insurance plan. For example, copays incurred under the pharmacy benefit are not credited towards the maximum annual out of pocket caps of the insurance plan. You should request a complete benefits investigation before determining who will provide therapy and in which site of service. The payer can provide this information or the you can speak directly with the payer’s customer service representative.

File a Complaint Against Your Health Plan

There are organizations that can help you if you are having a problem and are not getting the coverage you are entitled to:

California Department of Managed Health Care (DMHC)

The HMO Help Center is a part of the DMHC. The DMHC oversees HMOs and some other health plans in California. The HMO Help Center can help you with your complaint and can also provide you with an Independent Medical Review (IMR), if you qualify. Visit www.dmhc.ca.gov or call (888) HMO-2219. The HMO Help Center is open 24 hours a day, 7 days a week and can provide help in many languages.

California Department of Insurance (CDI)

The CDI regulates point-of-service health plans and certain Preferred Provider Organization (PPO) health plans. The CDI complaint program includes a toll-free number, dedicated to the handling of complaints and inquiries. Call (800) 927-HELP for all areas of California except area codes 213, 310, and 818, for which you should call (213) 897-8921. The CDI also provides a simple, standardized complaint form, which is available at www.insurance.ca.gov.

Medicare

Free individual counseling about Medicare and other health care issues is available through the Health Insurance Counseling and Advocacy Program (HICAP). HICAP counseling is available in every county in California. For counseling or more information call (800) 434-0222, or visit HICAP online at www.cahealthadvocates.org.

Medi-Cal Managed Care Office of the Ombudsman

The Medi-Cal Managed Care Office of the Ombudsman helps solve problems from a neutral standpoint to ensure that Medi-Cal patients receive medically necessary covered services for which plans are contractually responsible. The Ombudsman considers all sides in an impartial and objective way and develops fair solutions to healthcare access problems. Contact (888) 452-8609, or MMCOmbudsmanOffice@dhcs.ca.gov, or visit www.dhcs.ca.gov/SERVICES/MEDI-CAL/Pages/MMCOmbudsmanOffice.aspx.

**Model Letter 1:
Protest Drug Being Changed on or Switched from Drug List**

[Today's Date]

Re: [Your Name]
[Your Insurance Carrier / Health Plan / IPA Name]
Insurance ID Number: [Your Insurance ID Number]
Request for Continuation in Drug Coverage

Dear [Medical Director's Name],

I have been prescribed [Name of Drug] [continuously / intermittently] for the past [timeframe that you have been taking the drug] for [name of your medical condition]. Up until recently, I have received appropriate coverage from your insurance company for this important medication. However, I was recently informed that the drug [has been taken off your formulary / has been moved to a more expensive copayment tier]. This change makes it impossible for me to get this medication.

Given that this drug was previously approved for coverage for my condition, the law entitles me to a continuation of coverage under the same terms and conditions that existed prior to the change where (1) my doctor continues to prescribe that drug for me, and (2) the drug is appropriately prescribed and considered safe and effective for treating my condition. (Health & Safety Code Section 1367.22.) As I respond well to this medication, my physician continues to prescribe it for me. Should you have any further questions, my physician's name and telephone number are [Your Physician's Name] and [your physician's telephone number].

Under these circumstances, I am entitled to a continuation of my former coverage for this drug. Please contact me to confirm this fact. I can be reached at [your phone number].

Thank you very much for your attention to this important matter.

Sincerely,

[Your Signature]
[Your Name]

cc: [Your Physician's Name]

Model Letter 2: Appeal of Coverage Decision Regarding a Specific Drug

[Today's Date]

Re: [Your Name]
[Your Insurance Carrier / Health Plan / IPA Name]
Insurance ID Number: [Your Insurance ID Number]
Appeal of [] Determination Regarding Drug

Dear [Medical Director's Name],

For the reasons discussed below, my physician believes it is medically necessary that I take [name of medication]. Unfortunately, I cannot access this medication because of your company's decision to [action taken, e.g.: not include it on your drug list / place it on an expensive tier / require that I take other medications first]. I am writing to you to appeal this decision.

[Name of medication] is medically necessary in this case because it is the best and most effective medication for my condition. Indeed, a number of studies have recommended this particular drug, including [names of studies]. Further, the pharmacology of the drug your company is requesting that I take is potentially harmful to me. I have little tolerance for any changes in my medications and I have experienced [list negative effects] due to changes in drug regimens. Other harmful effects include [list other negative effects].

In addition, covering this medication now would be in your company's economic interest because [discuss any potential cost savings, e.g., the drug should make me healthier quicker / reduce the likelihood of hospitalizations].

My prescribing doctor clearly feels that my taking [name of medication] is in my medical best interest. My physician's name is [Your Physician's Name] and [he / she] she can be reached at [your physician's telephone number].

Thank you for your reconsideration and prompt attention to this matter. Please let me know if there are any additional steps I should take for this appeal.

Sincerely,

[Your Signature]
[Your Name]

cc: [Your Physician's Name]

Help Form

If you are having trouble getting your medications, please use this form to let the Neuropathy Action Foundation know about your experience. Completing the form can benefit you in two ways. First, the NAF can help you work with your insurance company to get the medications and therapies you are entitled to. Second, the NAF will keep track of the problems patients face, identify patterns and work to improve the system for everyone.

Just cut off this form on the dashed line, fill it out and call us toll-free at (877) 512-7262 to find out where to mail it.

1. Patient's name: _____
2. Patient's telephone number: (____) _____
3. Name of person asking for help (if not the patient): _____
4. Phone number of person asking for help (if not the patient): (____) _____
5. Insurance company name: _____
6. Insurance company member services telephone number (see your ID card): (____) _____
7. Patient's insurance identification number: _____
8. Name of drug that you are having trouble getting: _____
9. Diagnosis for which drug was prescribed: _____
10. Please explain fully the facts of your problem. Why are you having a problem? Did you appeal? Please attach photocopies of any letters from your insurance company and any other materials you believe are important.

11. AUTHORIZATION: I, _____, hereby authorize the Neuropathy Action Foundation to have possession of the above medical information and other information necessary to assist me with my dispute.



Signature

Date



Additional Consumer Assistance

There are a number of programs that help patients with their coverage problems. These include:


Health Consumer Alliance

 (310) 204-4900
 www.healthconsumer.org

Patient Advocate Foundation

 (800) 532-5274
 www.patientadvocate.org

Patient Services Incorporated

 (800) 366-7741
 www.uneedpsi.org



Neuropathy *Action* → Foundation

Awareness ▪ Education ▪ Empowerment

Toll free: (877) 512-7262

info@neuropathyaction.org

www.neuropathyaction.org

This document is to provide persons needing access to medications with general information. It is not intended to be, nor should it be, construed as providing specific legal advice. Persons needing such advice are urged to contact their personal attorney.

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