

GETTING THE MEDICATIONS YOU NEED

Understanding Your Rights¹ In Delaware

When choosing health insurance or trying to get coverage for your prescription medications, it is important to understand that gone are the days when your insurance company would pay for any and all medications any time you need them. Insurers offer a number of different products, all with different hurdles and rules that may require that you pay more for the very medications that are best for you. Your insurance company will give you something called an “Evidence of Coverage” that will explain the rules that apply to you. However, *appropriate medical treatment depends on many factors such as age, the nature and extent of the disease(s), ethnicity, genetic background, and patient preferences. Because of these differences, patients may not necessarily get the most effective care if their medication options are limited by what payers and other third parties believe is the most efficient.* For this reason, medical experts have raised concerns that insurance company rules could result in such things as a decline in health, and the substitution of less effective, but more toxic, medications.²

Below are answers to general questions regarding how prescription drug insurance works and what rights patients have to get their needed medications. Sample letters and useful contacts are also provided to help patients get what they need.

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 have expedited review for such cases. At the end of this document are some contacts for you to use when getting help, including the phone numbers of the relevant regulators. If you need urgent help, make sure you tell them this.

TYPES OF COVERAGE

1. **If my doctor prescribes a medication for me, does that mean my insurance company has to pay for it?**

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

¹ 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.

² See Stephen B. Soumerai, *Benefits and Risks of Increasing Restrictions on Access to Costly Drugs and Medicaid*, Health Affairs, Vol. 23, No.1 (2004).

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

BRAND NAME v. GENERIC MEDICATIONS AND SUBSTITUTIONS

2. What are brand name medications?

Brand name medications are the medications sold by the manufacturers that developed them after years of research, clinical trials and study. Depending on how long the medications have been on the market, they may no longer be protected by the patent laws, that is, the right to be the only medication with the same active ingredients. After the patent ends, generic medications--medications that try to copy brand name ones—may be sold to patients.

3. Why is there a push towards generic medications?

They are usually cheaper than brand name medications—that is why insurance companies prefer them. Ways that insurance companies use to promote them include a willingness to pay only for generic medications, requiring that you pay higher copayments for brand name medications, and even giving physicians a financial bonus if they meet a target generic prescribing rate.

4. I understand that they are cheaper, but are generic medications the same as brand name ones?

According to the US Food and Drug Administration (FDA), , a generic medication must have the same amount of the active ingredient of the brand name one, but may differ in other respects such as the way the medicine is released into your system, or the way it is formulated through added fillers such as flavors, preservatives, etc. Further, while the FDA approves generic medications 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 you.

The FDA allows a difference here of up to 20% from the brand name medication. See U.S. Food and Drug Administration, *Approved Drug Products with Therapeutic Equivalence Evaluations*, (27th Ed. 2007).

5. But are generic medications as good for me as the brand name ones?

They can be, but that is not always the case. Because of the real differences between the brand name medication and the generic one, there may be a medical reason why the generic version would not be as good for you. The American Heart Association, for example, is worried that substituting brand name medications with generic ones may be harmful, particularly with respect to antiarrhythmic and anticoagulation treatment.³ This concern is not surprising given that an independent study of members of a California Medicare HMO whose coverage changed to a generic-only benefit found that these patients experienced more hospitalizations overall.⁴ When deciding whether to take a generic medication, you should discuss this issue further with your doctor.

6. Is it true that sometimes the medication my physician recommends gets substituted for another drug, such as a generic one?

Yes. It can happen. For example, generic substitution occurs where a brand name medication is switched to a generic one. In Delaware, when a pharmacist receives a prescription for a brand name medication, the pharmacist may dispense a therapeutically equivalent drug product if the following conditions are met:

- (1) The prescriber, in the case of a written prescription, places the prescriber's signature on the signature line alongside the words "substitution permitted" or, in the case of a verbal prescription, states that substitution may be made,
- (2) The pharmacist informs the patient or the patient's adult representative that a generic medication has been dispensed which results in a monetary savings for the patient;
- (3) The pharmacist indicates on the prescription label the name of the manufacturer or distributor of the medication substituted, unless the prescriber otherwise indicates, and
- (4) The medication is therapeutically equivalent according to the United States Food and Drug Administration's "Approved Prescription Drug Products with Therapeutic Equivalents Evaluations" and its supplements. 24 Del. C. 2553.

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. This usually occurs where the prescribing

³ See American Heart Association, Kowey, M.D., et al., *Issues in Bioequivalence and Generic Substitution for Antiarrhythmic Drugs* (2007)

⁴ See Christian-Herman et al., *Effects of Generic-Only Coverage in a Medicare HMO*, Health Affairs, Web Exclusive, September 29, 2004.

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 Delaware regulations prohibit managed care organizations from offering incentives to a participating provider to provide less than medically necessary services to an enrollee. Delaware Title 18, Code 10.1.

DRUG LISTS

7. 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 an insurance company's medication list is to go to your insurance company's website and get it from the Internet. If you are already a member, you can also call your company's member services department. Their phone number is usually on your insurance identification card. For Medicare plans, you can use the Medicare Prescription Plan or Formulary Finder tool at www.medicare.gov or call the Medicare helpline (1-800-MEDICARE; 1-800-633-4227) and ask a customer representative to let you know what medications are covered and compare plans for you.

8. What if I am comparing plans and want to see their different medications lists?

Most companies are required by law to provide you with a list of medications that are covered by each of their products. This information can usually be accessed on their website or by calling their member services division.

9. But if the medication I need is on the list, does that mean that the insurance company will pay at least for some of it?

Not necessarily. Again, insurance companies offer many different types of products, many of which cover and exclude different medications. For that reason, many medication lists explain that just because a medication 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 medications are covered.

CHANGING OR "SWITCHING" MEDICATIONS ON THE LIST

10. Can my insurance company take medications off the formulary or preferred drug list?

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

11. What are my rights if I was covered for a medication and then it was removed from the list?

Unfortunately, there is no specific protection under Delaware law if this occurs, although if the medication is removed from the formulary, plans should give you the right to

appeal for medical necessity reasons. See discussion below. If your plan tries to switch medications, you can protest with a letter along the lines attached at the end of this document. (Model Letter 1.)

However, if a medication is switched to a more expensive tier (see discussion below on costs), the cost of the medication may be too expensive. In that case, the switch could mean that you cannot get your medications from a practical standpoint, unless the plan offers you a right to appeal. .

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 medication from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D medication, a plan must, among other things:

(A) Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

(B) 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. 42 C.F.R. Section 423.120.

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

COSTS

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

Assuming your insurance company covers the medication (remember, if it doesn't, you are responsible for paying 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 medications. This amount differs from plan to plan. The important thing to understand is that once this amount is reached, the plan will no longer help you pay for your medications 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 medications **before** your insurance company will help pay for any of them. So, if your plan has a pharmacy deductible of \$750.00, you will need to spend \$750.00 on medications before you pay a copayment and the plan pays the rest. These deductibles are usually in addition to the deductible you have for your general health care expenses. Often, these deductibles only apply if you use brand name medications.

Copayments – This is the amount you need to pay each time you get your medications. Again, plans have different rules here and the copayment can be a flat dollar amount or it could be a percentage of the cost of the medication. In preferred drug systems, your drug may be placed in a “tier” (level of preference) which may result in an increased co-payment. The higher the “tier,” the more you will need to pay, especially if you need a non-preferred brand name drug.

13. My plan has a limit on my out-of-pocket expenses. Do my medication costs count towards that limit?

Usually they do not. Again, it is important you know the rules of your plan.

LIMITATIONS/PRIOR APPROVAL

14. Other than costs, what types of rules can my insurer have before I can get my medications?

There are a number of things insurance companies do to help reduce costs and/or control your medications. Briefly summarized, these can include:

- Prior Authorization – Certain medications, even those on your insurance company’s drug list, need your insurer’s approval before your company will agree to help pay for them. If that is the case, your doctor will need to explain to the company why this medication is medically necessary for you. While most doctors are very busy taking care of their patients and find it difficult to do “battle” with insurance companies, it is important for you to work with your doctor to make sure that he/she advocates on your behalf to get any medications that you need. Note that this process may take time so you may need to pay for the entire cost of the medication until a decision is made.
- Step-Therapy – Some insurers may require that you try certain less expensive medications before they will cover the one your doctor initially recommended. If, however, it is medically necessary for you to use the “first-line” medication before trying the cheaper alternatives, again, your physician should be able to get a medical exception for you from the plan.
- Quantity Restrictions – Most insurers also set quantity limits on some of the medications that they will help pay for. Nonetheless, 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.
- Mail Order – Some plans may require that you use their preferred mail order pharmacies in order to get your medications. Delaware law specifically prohibits such a requirement as it provides “No insurer shall require a beneficiary, as a condition of payment or reimbursement, to purchase pharmacy services, including prescription drugs, exclusively through a mail-order pharmacy.” 18 Del. C. 7303.
- Off-Label – Some plans may deny coverage if the medication has not been

specifically approved by the FDA to treat your condition. Many states recognize the medical need for patients to receive medications under these circumstances. In Delaware, insurance plans that provide coverage for prescription medications must provide coverage for any outpatient medication prescribed to treat a covered person for a covered chronic, disabling or life-threatening illness if the medication:

- (1) Has been approved by the Food and Drug Administration for at least 1 indication; and
- (2) Is recognized for treatment of the indication for which the medication is prescribed in:
 - a. A prescription drug reference compendium approved by the Insurance Commissioner for purposes of this section; or
 - b. Substantially accepted peer reviewed medical literature.

Coverage of a drug required by this law must include coverage of medically necessary services associated with administration of the drug. 18 Del. C. 3350, 3566.

APPEALS

15. 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- 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 as to why you need a certain medication.
- Ask your employer for help – You may wish to get the help of your employee benefits manager or whoever else in your company works with your health plan in securing coverage. Because a number of studies and reports have concluded that rises in the copayments cut the use of medically necessary medications,⁵ many employers have worked with plans to reduce or eliminate copayments to “take not the cheapest medications, but the ones they need the most.”⁶ Purchasers of health coverage are increasingly realizing that getting the right care early on saves money in the long run.

⁵ Goodman, et al., *Pharmacy Benefits and the Use of Drugs by the Chronically Ill*, JAMA, May 19, 2004, Vol. 291, No.1.

⁶ See, *New Tack on Copays: Cutting Them*, Wall Street Journal, May 8, 2007.

- Appeal – First, if the best medication 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 medication 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 not explicitly stated in their rules.

Delaware law does not provide a specific appeal right for non-formulary medications, though plans should provide you with a general right to appeal decisions that prevent you from accessing your medication.

With respect to Medicare Part D plans, it is important to note that an easy process has been set up for enrollees and/or their physicians to use to help them get their needed medications. It is called the exception process. Enrollees can use this process for virtually any plan decision that restricts access to needed medications, such as requests for non-formulary drugs, requests for lower copayments, and requests to be relieved from quantity limits. Note, however, exception requests concerning formularies or tiering must be supported by a physician’s statement to support the request, i.e., that the “preferred” medication is effective for the enrollee’s condition and that it would have an adverse effect on the enrollee. The Medicare program has provided a model form for enrollees to use when seeking exceptions with their plan—a copy of which can be found at <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/ModelCoverageDeterminationRequestForm.pdf>. Enrollees who have been denied the medication through this process still have the right to appeal. To start the appeal, ask the plan for its appeals process—usually this consists of writing a letter within 60 days of the denial requesting a redetermination and explaining why the access to the medication was denied and why that decision was wrong.

Regardless of whether it is Medicare or a private insurance company, you need to make sure that the matter is appealed. While your doctor should help you with this, only you can take charge of the appeal and only you can be sure that it is being done. In your appeal, you need to present facts. For example, make it clear that a formulary or preferred medication has failed you and explain why. Explain any bad reactions you may have had from a formulary medication, including generic medication. Provide as much detail as possible for the medical reasons supporting your appeal. 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 as a guide.

CONTACTS

In addition to us, there are people that can help you if you are having a problem and are not getting the coverage you need:

CONTACT THE REGULATOR	REGULATOR	CONTACT NUMBER	WEBSITE	WHAT THEY REGULATE
	Department of Insurance	1-800-282-8611	www.delawareinsurance.gov	Insurance plans
	Department of Labor (DOL)	1-866-444-EBSA (3272)		ERISA plans
	Health Insurance Counseling and Advocacy Program	1-800-336-9500		Medicare plans in Delaware

There are a number of programs that help patients, particularly low-income ones, with their coverage problems, including:

CONTACT CONSUMER ASSISTANCE PROGRAMS	PROGRAM	CONTACT NUMBER	WEBSITE
	Patient Advocate Foundation	1-800-532-5274	www.patientadvocate.org

MODEL LETTER 1 – PROTEST OF DRUG BEING CHANGED ON OR SWITCHED FROM DRUG LIST

Date:

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

Dear (Medical Director)

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

This new formulary limitation impairs my ability to receive medications important to handling to medical condition. When a non-formulary alternative in medically necessary and appropriate, as is the case here, I should be entitled to an exception.

(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 (identify studies). Further, the pharmacology of the drug your company is requesting that I take is potentially harmful for me. I have little tolerance for any changes in my medications and indeed, I have experienced (identify problems) due to changes in drug regimens. Other harmful effects include (explain).

In addition, covering this medication now would be in your company’s economic interest because [discuss any potential cost savings, e.g., the fact that the drug should make you healthier quicker, reduce hospitalizations, etc.]

As I respond well to this medication, my physician continues to prescribe it for me. My physician’s name and telephone number are _____ should you have any further questions.

Under these circumstances, I am entitled to a continuation of my former coverage for this medication. Please contact me to confirm this fact. I can be reached at _____

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

Patient’s Name

cc: (Physician)

MODEL LETTER 2 - APPEAL OF COVERAGE DECISION REGARDING A SPECIFIC DRUG

Date:

Re: Patient Name:
Insurance Carrier / Health Plan / IPA
Insurance ID Number:
Appeal of ____ Determination regarding Drug

Dear [Medical Director]

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, i.e., not include it on your drug list, placing it on an expensive tier, requiring that I take other medications first, etc.) 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 (identify studies). Further, the pharmacology of the medication your company is requesting that I take is potentially harmful for me. I have little tolerance for any changes in my medications and indeed, I have experienced (identify problems) due to changes in drug regimens. Other harmful effects include (explain).

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

My prescribing doctor clearly feels that my taking (name of medication) is in my medical best interest. My physician's name is _____ and he/she can be reached at _____.

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,

Patient's Name

cc: (Physician)