



Writing to Win: Overcoming Health Insurance Challenges

Training Materials

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Introduction and Disclaimer

These materials have been compiled using specific examples for purposes of illustration. However, the information set forth here is applicable to any drug, device or other treatment – particularly those that the insurance companies believe are “experimental, investigational or unproven.”

These materials are informational only, and are not to be considered legal advice or representation. They are not intended to create a formal attorney-client relationship, nor are they intended to solicit clients. These materials are not intended to be a substitute for legal advice about any particular case; they are intended solely as information.

Throughout these materials, I will use specific examples of a treatment for which insurance coverage is difficult to obtain. This should not be considered as an endorsement of the efficacy of such treatment. Neither I nor Advocacy for Patients with Chronic Illness, Inc. has any beneficial or financial interest in any treatment mentioned here.

No third party is responsible for the content of these materials. Any and all opinions, errors or omissions, and all opinions expressed, are the solely those of the author unless otherwise expressly attributed to a third party.

After the training, you should feel free to contact me for assistance, especially on appeals. It may just be that a cover letter from a lawyer is going to be what it takes. Advocacy for Patients will be here to provide free support for the benefit of any patient, as always, whether or not the particular matter is grant funded. Please feel free to contact me directly if you have questions, or if you feel that our intervention is necessary in any particular case.

We hope that this training will assist you (and your doctors) as you continue to navigate the ever more burdensome health insurance process.

Thank you.

Jennifer C. Jaff, Esq.
Advocacy for Patients with Chronic Illness, Inc.

Basic Approach

Nationally, approximately 70% of health insurance appeals are granted. Advocacy for Patients construes this statistic as proof that the insurance companies deny many claims with the assumption that at least some denials will not be appealed. Advocacy for Patients with Chronic Illness, Inc. has an extraordinary track record with insurance company appeals – over 90% of our appeals have been granted.

Why are we so successful? Because we **package an appeal** like nobody else does. We include not only a letter written and signed by an attorney, but we enclose relevant medical records containing objective medical information, published medical research, and, hopefully, a letter from a treating physician (or more than one, if appropriate).

Most physicians and insurers we work with are surprised by our approach. Insurers often ask if I would like them to send the file to the appeals unit, and are surprised that I intend to submit a significant packet of information, including letters from doctors and medical records, along with my cover letter. Physicians think that, when I ask for a letter, I am just going to send their letter on to the insurer. We **never** just report a patient's symptoms without more. And we **never** just send a doctor's letter without any supporting objective medical information.

Types of Insurance Policies

There are two main types of employer-based health insurance policies – fully-funded insurance, which is what you think of as insurance. The employer purchases insurance from an insurance company and the insurance company pays claims out of its pocket. The second type of employer-based health insurance policy is self-funded, where the employer hires an insurance company to administer the plan, but the employer – usually large employers – actually pays the claims out of its own pocket.

Usually, you can't tell which type of policy you have. If your policy has a "certificate of coverage," it's a fully-funded plan; if instead you get a "summary plan description," it's a self-funded plan.

Why does this matter? First, if your employer self-funds, then your employer can decide to cover a treatment that the insurance company does not want to cover. In such a case, an appeal to human resources may solve your problem.

Second, generally, a state external appeal process will not apply to a self-funded plan. The next section explains about external appeals.

The Appeal Process

Most insurance companies give you two levels of appeal. The first appeal usually is due within 180 days of the denial of coverage. The second is usually 30 to 60 days. Thus, it's very important to gather medical records and other materials early in the process. If you wait for the second level appeal, you may have only 30 days to do all the work. This is a challenge.

In most states, there also is an external appeal. This is an appeal to the State Insurance Department that you can file after you have exhausted all of your internal, insurance company appeals.

External appeals vary greatly. Some only cover HMOs; some only cover determinations that treatment is "experimental." Some charge a small fee; some return the fee if you win. In short, they are all over the map. Contact your state Insurance Department for more specific information. NOTE: that external appeals often have a strict 30 day deadline. Be careful not to exceed time limits.

Necessary Objective Evidence

You should do your best to emphasize **objective medical information** when fashioning an appeal.

What is objective medical information? Anything other than subjective complaints of symptoms. If you think like an insurance company, then a patient who claims to vomit 10 times a day is exaggerating. However, weight loss as measured by and/or in a physician's office is objective evidence and, therefore, is reliable. If you think like an insurance company, almost any complaint of pain should be discounted. However, a gastric emptying study, a barium study, endoscopy and pathology reports all are objective evidence upon which insurance companies will rely.

In all appeal stages, you should attach objective medical information.

This does not mean that you should not describe your symptoms; only that you should try your best to support the subjective complaints of vomiting, for example, with objective evidence of, say, weight loss and electrolyte imbalance.

Experimental, Investigational and Unproven

Many noncoverage decisions are justified based on the claim that the treatment is experimental, investigational or unproven. Most commonly, the “unproven” justification is provided.

For any treatment, it is important to note what the treatment is intended to do. This should be stressed since a treatment might be proven for one use and unproven for another.

There are two things you can do to rebut the claim that the treatment is unproven.

First, **you should submit peer-reviewed published studies.**

Second, most insurance policies have an **exception in cases in which the medical condition is life-threatening**. If your condition is grave and you believe a treatment is necessary to save your life, then you should argue that the exclusion of unproven treatments does not apply.

Request for Prior Authorization

As you know, insurance companies require that doctors obtain pre-approval for certain medications, devices, and other treatments. Some companies call it pre-determination, and others prior authorization. The process is the same regardless of the name it is given.

Although it seems that certain insurers do not read these requests – they see the CPT codes and they deny without regard to the patient’s medical condition – the request for pre-determination should be taken seriously. Even if the insurer does not carefully evaluate the request, the request for pre-determination will bolster your appeal, as explained below.

In any event, the request for pre-determination is important, and should be handled as thoroughly as possible. If an insurer reverses enough non-coverage decisions made at the prior authorization stage, ultimately the insurer may be convinced to conduct a closer scrutiny of the pre-certification phase of the process rather than simply denying the claim without regard to the patient’s medical condition.

There is no down side to providing a strong request for pre-determination. Best case scenario, it will eliminate the need for an appeal; worst case scenario, the file will already contain most, if not all, of the pertinent information, making an appeal easier.

Explanation of Benefits

When your insurance company processes a claim and does not pay it in full, you get an explanation of benefits or EOB. The appeal instructions are on the back of the EOB. The appeal process itself typically is the same as if appealing the denial of a request for prior authorization.

Outline of Request for Prior Authorization
To be Filed By Your Physician

As noted above, your doctor's request for pre-determination may serve one of two purposes: first, it might actually be considered based on the information and records you submit; or second, it might position you well for an appeal. Either way, this step should be taken seriously.

The following information should be provided in a request for pre-determination:

- Patient's Name (and name of insured if not the patient);
- Patient's Insurance ID number, Social Security number and date of birth;
- Physician's specialty and years of experience;
- Physician's experience with the particular device, medication or treatment;
- Patient's diagnosis, including **both subjective and objective support** for the diagnosis (weight loss, recent test results, endoscopy reports with pathology, etc.);
- What treatments have been tried over what period of time (go back to the date of diagnosis and describe all that has been tried and failed);
- Summary of the medical literature, preferably including copies of the literature (both summary and copies of literature are enclosed);
- Why the doctor believes this therapy or service is clinically indicated for this patient at this time.

A couple of points to emphasize.

First, **the insurance companies want objective evidence**, not subjective evidence. A patient's complaint of reflux, vomiting, nausea, diarrhea all are subjective in the eyes of insurance companies. Results of a colonoscopy or endoscopy with pathology, barium studies, CT scans and other quantifiable tests are objective and, thus, more reliable in the eyes of the insurance companies.

It is not enough for you to state in your letter the results of these tests. The written reports of these objective indications should be attached to and submitted with your request for pre-determination.

Similarly, **a brief review of the medical literature** with copies of the articles is appropriate even at this early stage, especially if your doctor has reason to believe that the insurer will deny coverage by claiming the treatment is "experimental, investigational or unproven."

The Appeal: First Steps

If your request for pre-determination is **denied**, you should do a number of things before you write the appeal letter:

Step 1: Assess the Situation

- Was this an automatic “administrative” denial – i.e., the insurer never really looked at the request for pre-determination but instead simply denied the claim as soon as they saw the CPT codes? If so, you probably need help with an appeal.
- If instead, you got a denial that provided enough detail so that you can identify the questions the insurance company had that require a response, you can simply send copies of a test results and/or other “objective” diagnostics (including weight loss), then follow the appeal instructions in these materials. You may be able to handle the appeal yourself.

How can you find this out? Every denial letter contains a paragraph offering to provide a copy of the file on the claim, including the insurer’s clinical criteria. **Always request this file.** This step is critical; do not omit it.

Step 2: Prepare the Materials. You should prepare the information we will outline in these materials and either submit them to the insurer if you are comfortable handling the appeal yourself, or forward them to Advocacy for Patients as soon as possible. This will include the request for prior authorization and copies of the materials referenced in that request, as explained in more detail below. If you wish to involve us, please fill out the enclosed **Medical Release and Authorization form.**

Step 3: Meet the Deadline for Filing an Appeal. Be sure to note the deadline for filing an appeal. Some insurers send the denial to the doctor who requested the prior authorization only. Although they should send a copy to the patient, it does not always occur. Once the deadline for appealing passes, there is nothing more to be done.

An insurer may grant an extension of time to appeal, although some state laws require insurers to resolve an appeal within a certain number of days, in which case it is more difficult to obtain an extension of time. If you think you may need more time, do not wait until the deadline has passed in order to ask for it. If an insurer grants extensions, it most likely will do so only if you ask before the initial deadline has passed.

Step 4: Work with All of Your Physicians. When Advocacy for Patients writes an appeal letter challenging a denial of coverage, we rarely end with the physician who submitted the request for pre-authorization. In a situation involving surgery, for example, typically, the patient will have been referred to the surgeon by a physician who has treated the patient over a longer period of time. That physician will have more records than the surgeon, and, in particular, may have a better record of all the things that have been tried and failed before recommending Enterra Therapy.

ERISA FULL AND FAIR REVIEW

The Employee Retirement Income Security Act (ERISA) is best known for its regulation of pensions. However, ERISA applies to any employee benefit plan sponsored by an ERISA-governed employer, including health insurance plans. Although not all health insurance plans are governed by ERISA, ERISA's standards are persuasive authority even as to a plan that is not governed by ERISA.

Although much of ERISA is hyper-technical, there are **two** main principles that you should know about, both of which flow from ERISA's requirement of "full and fair review."

Principle number 1: Insurers must provide a copy of their entire file, including clinical criteria. Insurers must provide a free copy of anything they relied on, as well as information in the file on which the insurer did not rely (i.e., information supporting coverage that the insurer rejected). The purpose of this requirement is to enable patients and their representatives to file an appeal that responds to the information upon which the insurer relied, as well as to know what additional information to provide.

This requirement includes the rule that insurers must produce a copy of their clinical criteria. This is critical. If you have the clinical criteria, you can explain how you meet those criteria. Otherwise, you are left guessing as to what the insurer's standard is for approving coverage.

When a patient requests a copy of the file and clinical criteria in writing and these materials are not produced within no more than thirty (30) days, you can allege that the insurer has violated ERISA.

Principle number 2: Insurers must explain the reasons for a noncoverage decision. The purpose of this requirement is to ensure that an appeal can address the issues raised in the noncoverage decision. When an insurer does this correctly, the denial letter includes a sufficiently detailed statement of the insurer's reasons so that you will know what to argue in your appeal. A statement that the device is unproven is insufficient.

The courts have interpreted ERISA's "full and fair review" provisions as being quite strict. If the insurer violates these rules, the courts typically do not send the case back to the insurer with an order to do it right the second time. Instead, the majority of courts simply grant the benefits. Therefore, ERISA's "full and fair review" provisions can be a tremendously useful tool in an insurance appeal.

If you believe you have a "full and fair review" violation, please contact Advocacy for Patients for assistance. You will need a lawyer to brief this violation. In your letter, you should state that you are constrained from responding to the merits of the denial because the insurer has failed or refused to produce its file, including its clinical criteria, or because the reason for the denial is so general that it is impossible to provide a response to that reason.

The Insurance Policy Language

Among the documents that should be produced in response to a request for a copy of the file, including the clinical criteria, is a copy of the certificate of coverage or summary plan description. It is important that you review the policy language for two purposes.

First, look at the exclusion identified by the insurer as a justification for the denial. Believe it or not, I have caught insurers failing to apply the right policy language.

Second, review the policy for anything that would justify an exception. As explained above, many, if not most, policies will provide for an exception when the patient's condition is life-threatening. There may be other exceptions that apply in your client's case.

For these reasons, it is critical that you carefully review the language of the health insurance policy.

Outline of the Appeal Letter

If your doctor prepared a request for prior authorization according to the suggestions provided in these materials, you are a long way towards preparing the appeal. The content of an appeal letter is not very different from a request for prior authorization. Again, you should include all of the following elements:

- Patient's Name (and name of insured if not the patient);
- Patient's Insurance ID number, Social Security number and date of birth;
- Your specialty and years of experience;
- Your experience with the particular device, medication or treatment;
- The patient's diagnosis, including **objective** support for the diagnosis (weight loss, recent test results, endoscopy reports with pathology, etc.);
- What treatments have been tried over what period of time (go back to the date of diagnosis and describe all that has been tried and failed);
- Summary of the medical literature, preferably including copies of the literature (both summary and copies of literature are enclosed);
- Why you believe this therapy or service is clinically indicated for this patient at this time.

There are **two main differences** between the request for prior authorization and the appeal.

First, you should provide an update on your condition, stressing how it is worsening due to the delay created by the need to appeal.

Second, you should tailor your response to the insurer's reasoning and/or file. Here are a few examples:

- * If you request a copy of the file and finds that the insurer did not have copies of the most recent objective medical evidence, you should emphasize that evidence in your appeal letter.
- * If it appears that the insurer ignored some of the scientific evidence, you should

summarize and attach copies of the articles they did not consider.

- * If the policy language creates an exception for treatment of life-threatening illness, you should point that out.
- * And when you cannot get the insurer's file, including the clinical criteria, you should say that the insurer failed to provide you with enough information so that you could tailor your response appropriately. In other words, think ERISA "full and fair review."

Conclusion

Advocacy for Patients works with patients every day, most of whom are smart enough to file an appeal themselves, but they are not sure how to do so. It is our hope that, with the assistance provided here, you will have a better sense of what will work. Although preparation of requests for prior authorization and appeal letters is burdensome, the more you can routinize the process, the less time it will take to provide these documents.

And when all else fails, you now have been introduced to Advocacy for Patients with Chronic Illness, Inc. We never have turned a patient away, nor do we intend to do so in the future. Thus, we are pleased to do whatever we can do to assist you to ensure that you are able to obtain the medical treatment you need to live a healthy and productive life.

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SAMPLE APPEAL LETTER

This sample is an example of a letter that a patient or physician would write in support of an appeal from a non-coverage decision. **Please note:** your letter must be individualized. **Do not use this letter as a form letter.** You should use this sample to ensure that you are providing all of the necessary information. However, it is critical that you not submit a cookie-cutter appeal letter that is not tailored to the particular patient.

INSURER
ADDRESS

RE: Patient Jane Doe
INSURANCE ID NO.

Dear Appeals Coordinator:

I am writing to appeal your November 1, 2005 denial of coverage for XIFAXAN.

Essentially, your's rationale for denying coverage is that XIFAXAN is not FDA approved for the treatment of Crohn's disease. This is not a credible rationale. There are only two drugs FDA approved for treatment of Crohn's disease: Prednisone and Remicade. Every other drug – Asacol, Pentasa, Colazal, 6-MP, Azothiaprine, Flagyl, Cipro, Humira, Nexium, Protonix, Prevacid, Zofran, Phenergan, etc. – used to treat Crohn's disease is used off-label, without FDA approval for this use. Yet, these drugs are covered by you and every other insurance company or payment source including Medicaid and Medicare. Therefore, the fact that XIFAXAN is not FDA approved for the treatment of Crohn's disease cannot possibly be the real reason for the denial of coverage. If that were the reason, you would not pay for any of these other drugs, either.

My enclosed medical records show that I have active Crohn's disease throughout my upper GI track, well into my ileum. I enclose the report of a May 2005 capsule endoscopy showing abnormalities from the esophagus through the ileum. There is no question that I have active Crohn's in my small intestine.

In order to respond to coverage denials of XIFAXAN, I wrote to the distributor of XIFAXAN in the United States and obtained the enclosed materials, which cite published peer-reviewed literature. As you can see, XIFAXAN is particularly useful in treating active Crohn's in the small intestine. Rather than being absorbed into the bloodstream, XIFAXAN acts as a topical treatment for Crohn's in the small intestine. Not only have the studies of use of XIFAXAN in treating Crohn's showed great promise, but perhaps most importantly, **I was given XIFAXAN samples, and the XIFAXAN actually did alleviate my nausea and vomiting.**

As the enclosed materials explain, there is significant evidence supporting the view that intestinal flora play a role in Crohn's disease. Thus, antibiotic therapy is entirely routine at this time. Cipro and Levaquin work for some patients, but I have been on both Cipro and Levaquin for extended periods of time, as I am sure your records show. Not only have they not helped to control my Crohn's disease, but because these antibiotics are absorbed systemically, there are serious consequences to long-term use, including development of resistance to these medications.

XIFAXAN provides an alternative as a nonabsorbable antibiotic. It has been shown to target bacteria that may contribute to Crohn's disease. Unlike absorbable antibiotics, it does not induce resistance. Data from an open-label study of the effect of XIFAXAN on Crohn's disease is promising. Seventy-eight percent of patients showed marked improvement, and remission was induced in roughly half of the patients. Patients reported a marked decrease in symptoms.

Other studies are equally promising. A study of a small number of patients with severe Crohn's disease showed improvement in symptoms in as little as one week. Another showed that patients with ileitis and ileocolitis improved dramatically.

Although XIFAXAN remains under consideration for the treatment of Crohn's disease, my symptoms improved when I used the samples my physician was able to provide to me at no cost. I have been on prednisone, 6MP and Pentasa. Although I was reluctant, I underwent a month-long trial of prednisone recently, to no avail. The only thing that has helped my current symptoms has been XIFAXAN. Thus, we have empirical evidence that tells us that this drug will help me. This evidence outweighs the fact that the use of XIFAXAN in treating Crohn's disease remains under consideration.

Crohn's disease is one of a cluster of diseases about which medical science is learning more each day. New treatment modalities are being developed, and with such an insipid disease, it is nothing short of cruel to prevent a patient from obtaining safe new treatments as they become available. Here, because we know that XIFAXAN works for me, there can be no good reason to refuse to allow me to obtain this treatment.

It is my understanding that the prescribing physician, Dr. Peter, spoke with a representative at INSURER at some length about this claim, and he remains willing to do so again.

There is no alternative to XIFAXAN on your formulary because there simply is no other antibiotic that is nonabsorbable that has shown promise in treating Crohn's disease. For these reasons – and especially because we already know that XIFAXAN helped to alleviate my symptoms – I ask that you reverse INSURER's decision and grant coverage for this important new treatment of Crohn's disease.

Sincerely,

Patient

MEDICAL RECORDS RELEASE AND AUTHORIZATION

I, _____, do hereby give my permission for disclosure of any and all of my medical records and/or discussion of my medical condition as it relates to insurance or publicly funded benefit programs.

This release permits the following health care providers to disclose any and all of my medical records, as set forth below (list names of health care providers):

Name: _____

Address: _____

City, State, Zip: _____

Phone: _____ Fax: _____

Name: _____

Address: _____

City, State, Zip: _____

Phone: _____ Fax: _____

Name: _____

Address: _____

City, State, Zip: _____

Phone: _____ Fax: _____

This release permits the following insurer to discuss any and all information regarding claims, requests for authorization, appeals, and/or other matters:

Insurer: _____

Insurance ID Number: _____

Social Security Number (if different): _____

Date of Birth: _____

Any and all records in the possession of the above-named health care providers, and any and all matters pending before the above-named health insurer, including but not limited to filing an appeal on my behalf, may be disclosed to and/or discussed with the following:

Advocacy for Patients with Chronic Illness, Inc.

18 Timberline Drive

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(860) 674-1370 (phone)

(860) 305-9835 (cell)

(860) 674-1378 (fax)

I understand that, if there is a charge for copies of my medical records, I will be responsible for the cost of providing copies of those medical records.

This release shall remain in place until I have obtained authorization and payment for medically necessary services. I understand that, my health care and future payment for my health care will not be affected if I do not sign this form, except that Advocacy for Patients with Chronic Illness will not be able to advocate on my behalf without this Release and Authorization. In addition, I understand that I may revoke this authorization at any time by giving written notice of my revocation to the health care provider(s) and insurer(s) listed above. I understand that such revocation will not affect any action the health care provider(s) and insurer(s) listed above have taken in reliance on this authorization prior to receipt of my revocation, and that such revocation will not prejudice any and all claims and/or benefits to which I otherwise am entitled.

The information used or disclosed pursuant to this release and authorization may be subject to re-disclosure by the recipient and may no longer be protected by the Privacy rule.

This release applies under state and federal law, including but not limited to HIPAA privacy regulations.

I have read and understand the contents of this document and am hereby providing my agreement to the terms of this Authorization.

Date

Patient Signature
Patient address: _____

Telephone: _____