

Plowing through the paperwork: a guide for families and patients with IBD¹

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OVERVIEW

Even though most children and young adults with inflammatory bowel disease lead healthy and productive lives, it is common for such children to have periods of severe illness that interfere with school, activities, and work. During these periods, a family member or caretaker may also need to take time off from work to care for their sick child.

These periods of severe illness or hospitalization are often very stressful for children and parents. Your child may be thinking *"How will I ever get back to school?"* Parents or caretakers may be thinking *"Will I lose my job?"*, or *"What if insurance denies my child's medications?"*

The information provided in this guide will help you understand what options are available to assist your family during these difficult times and how the laws can help.

Please note, the following discussion is based on the laws of the United States of America, and does not apply to other countries. In addition, there may be state laws that affect these topics which are not discussed here.

This guide reviews:

- I. Educational accommodation plans (504 plans)** – plans that can modify a student's schedule, provide for extra help, and return a child to their normal school routine
- II. Patient assistance programs** – help with medication financing and medication co-pays
- III. Family and Medical Leave Act (FMLA)** – allows for legally approved time off from work without fear of losing one's job
- IV. Insurance Options** – reviews insurance options available for patients with IBD and some of the federal laws about insurance.
- V. Letters of medical necessity** – inform an insurance company of the need for a particular treatment

For additional information, the following resources are available:

¹Note: Nothing in this document should be construed as the giving of legal advice. This is informational only. If you have a problem that you believe requires legal attention, you should seek the advice of an attorney, preferably in your state.

1. Advocacy for Patients with Chronic Illness (Jennifer Jaff, Esq)
www.advocacyforpatients.org
2. Know your Rights: A Handbook for Patients with Chronic Illness (2008 edition). Available from: www.advocacyforpatients.org or www.Amazon.com.

I. Educational Accommodation Plans

What are Educational Accommodation Plans?

Educational Accommodation Plans are plans that provide for changes in a child's normal school routine to accommodate a child's disability.

According to Section 504 of the Rehabilitation Act of 1973, children are entitled to a "free appropriate public education" regardless of the nature and extent of their disability. A child has a "disability" (as defined by Section 504 and the Americans With Disabilities Act) if he or she is substantially limited in a major life activity.

Under the 2008 amendment to the Americans With Disabilities Act (ADA), bowel and digestive functions are major life activities. In addition, an episodic illness is disabling when in remission if it would be disabling when active. This means that IBD is considered a disability for the purposes of Section 504.

The US Department of Education regulations about Section 504 plans are divided between Preschool, Elementary and Secondary Education, and Postsecondary Education.

Preschool, Elementary and Secondary Education:

- Section 504 refers to various educational settings. When possible, disabled students will be educated, have meals and participate in activities with other students, in the same facilities. If a child has to use a facility other than the usual classroom, it must be as comparable to the usual classroom as possible.
- A Section 504 plan can include proximity to a bathroom, an anytime bathroom pass, stop the clock testing, tutoring or other assistance when a child is unable to attend school due to illness, and so on. The aim of accommodations under Section 504 is to provide the child with a level playing field. Any accommodations under Section 504 must be provided for free.
- The federal regulations allow for your child to have a formal evaluation before he/she is provided with an educational accommodation plan. Such formal evaluations rarely occur under Section 504, although they are required under the Individuals with Disabilities Education Act (IDEA).
- If a child requires special education, then the plan that will be written will be an Individual Education Plan (IEP) under the IDEA. A Section 504 plan does not and cannot include special education services. However, 504 accommodations can be written into IEPs.

Postsecondary Education:

- Section 504 and the ADA require that undergraduate colleges prepare a plan to accommodate the student's disability.
- The regulations prohibit discrimination in admissions and recruitment. This means that colleges cannot exclude disabled students or set quotas (limits) for admission of disabled students.
- Disabled students cannot be excluded from any academic, research, occupational training, housing, health insurance, counseling, financial aid, physical education, athletics, recreation, transportation, or other extracurricular activities.
- Academic adjustments must be made so as to eliminate and/or protect against discrimination. Adjustments may include giving students more time to complete their degree requirements. Exams and evaluations may also be changed to ensure that the results of the evaluation reflect the student's performance, not his/her disability.
- Housing and financial assistance must be provided to disabled students to the same extent as they are provided to non-disabled students.

- Note that courts tend to defer more to colleges than to elementary and secondary schools regarding accommodations that schools claim affect academic integrity.

How does a child get a Section 504 plan?

If you want a Section 504 plan for your child, you must request a Section 504 meeting. The Section 504 team will include school officials, all or some of the student's teachers, and parents.

How is a Section 504 plan created?

A Section 504 plan is created by the team. You may bring a draft of a plan with you to the meeting, or the school may prepare the first draft. It is important to remember that Section 504 plans are the process of negotiation. There is nothing that must be included, and nothing that cannot be included.

What if the Section 504 plan doesn't work?

If you agree to a plan and it turns out to be insufficient, you can request another Section 504 meeting.

If you are unable to reach an agreement with the school about the Section 504 plan, you must follow any procedures the school district offers for dispute resolution (such as a hearing). If you are still dissatisfied with the school district's response, you may file a complaint with the U.S. Department of Education Office of Civil Rights at <http://www.ed.gov/about/offices/list/ocr/complaintintro.html>.

Problem Areas for Patients with IBD

Patients with IBD face two issues that are not well addressed by the law.

First, children who do well in school are expected not to need help. According to IDEA, the definition of a "child with a disability" is a child who, because of his/her disability, needs special education and related services. A student is not considered a "child with a disability" if he/she is performing well academically and does not need special education. Because many children with IBD do not suffer academically, they may not be covered under IDEA. However, children with IBD are still eligible for accommodation plans under Section 504.

Second, neither statute (Section 504 or IDEA) provides guidance for children with a chronic disease that remits and relapses (flares). The 2008 amendments to the ADA make a big difference here by stating that episodic illnesses are disabilities. As with any chronic illness, there will be times when a student needs home tutoring and other times when the student has no need for assistance. This presents a challenge for both the parents and the school since a Section 504 plan is not intended to apply only some of the time. Flexibility is difficult to build into a plan.

Disabilities can be temporary but still disabling. However, getting the school to respond quickly to constantly changing circumstances is a challenge. A plan under Section 504 may include accommodations such as seating placement, extended time for testing, adjustment of class schedules, use of aids such as tape recorders, class and/or homework assistance, administration of medications, behavioral support, tutoring, etc. Elements of such a plan are present but the difficulty is coordination and timing.

How can your child's health care team help?

Most school teachers and administrators are dedicated professionals whose goal is to educate children. When a child is absent and/or not performing in school, school professionals may suspect malingering (making up or exaggerating symptoms).

If you give permission, your child's doctor or social worker can support your child by calling or writing to the school about your child. Once a school administrator hears from a health care professional, they will usually be more sympathetic to your child's needs and issues.

- A sample letter of support for a 504 plan is attached (See Section V, Letter #1). Bring this letter in to your child's doctor and ask him/her to adapt it for your child.
- Your child's doctor or social worker can also speak to school administrators and tell them about your child's disability and medical history with IBD (including symptoms, medications, and hospitalizations). **While such a call is not a substitute for a letter in support of a 504 plan, 5 minutes on the phone may save 5 hours of paperwork.**

What about college?

Students with IBD who graduate from high school and go to college sometimes require assistance, and are on their own for the first time. As mentioned above, section 504 plans apply to undergraduate colleges. Most Universities and Colleges have a Disability Office where the student can register. Making the school aware of the students' illness and possible complications that could occur prior to school starting will help avoid possible problems during a time of a flare. A plan can be made with the Disability Office as to how a student should communicate with their professors and how school work can be made up in case an illness occurs.

II. Patient Assistance Plans

What are Patient Assistance Programs?

Patients with chronic illnesses such as IBD often have health-related expenses that add up over time. In addition, families of patients with IBD may go through periods without work or health insurance.

Patient Assistance Programs help patients and families who do not have insurance or do not have enough insurance. Some programs help patients access medications for little or no cost, based on financial eligibility. Other programs help reimburse some expenses that accumulate (add-up) due to additive co-pays, so that it is less likely a patient or doctor has to postpone a necessary test, procedure or office visit.

Free Medications

Almost all pharmaceutical (prescription drug) companies that manufacture medicines run a patient assistance program. To qualify for these, patients must show they have no insurance, or have been denied coverage of a medication by their insurance company. Patients or families must also provide proof of income.

Patients or families can start the applications, but a portion of the application must be filled out and signed by the prescribing doctor. Applications often take 3-4 weeks for approval.

NeedyMeds

www.needymeds.org

- NeedyMeds has a lot of information and is the easiest site to use. The website keeps an updated master list of every pharmaceutical company, brand name medication, or generic medication that has an affiliated patient assistance program. The website provides a direct link to each program's website and contact information (if relevant).

RXHope (732-507-7400)

<https://www.rxhope.com/Patient/MedSearchHome.aspx>

- RXHope is a similar program that helps facilitate the process of finding and applying to patient assistance programs for certain medications. A health care professional or a family can set up a free account to register with the website and begin the process.

Partnership for Prescription Assistance (888-477-2669)

<https://www.pparx.org/Intro.php>

- This website has separate sections for patients, caregivers, or physicians. The website links to the relevant patient assistance programs and can help you complete forms online.

RxAssist, 401-729-3284

<http://www.rxassist.org/search/default.cfm>

- This website has a searchable database of patient assistance programs. You can search by drug name or pharmaceutical company. Once you find which company makes the medication you need, you can write them and ask them for assistance with getting medication.

Co-pay Assistance Programs

There are separate programs available for patients or families who have insurance, but with premiums/co-pays that add up when dealing with recurring costs. To qualify, patients or families must provide proof of income.

Patients or families must start the applications, but there is a section to be filled out by the doctor who is conducting visits, ordering lab work, etc. These programs usually work in a reimbursement format. If a family is approved, they must send in receipts for care provided.

Patient Access Network Foundation (1-866-316-7263)

www.patientaccessnetwork.org

- This program can provide assistance for Crohn's patients, but does not provide assistance for patients with ulcerative colitis.
- The program only covers the costs of medications or infusions.
- Benefits under this program are limited to \$4,000 per year for Crohn's patients, but eligible families can continue to re-apply each year.
- This program can run as a reimbursement program for expenses already paid by the family, or pay expenses directly to a physician or hospital if coordinated by the family.

Patient Advocate Foundation (1-866-512-3861)

<http://www.copays.org/>

- This program provides assistance to patients with either Crohn's disease or ulcerative colitis.
- The primary program helps with only pharmaceutical services, such as medications, injections and infusions.
- Patient Advocate Foundation has a separate branch of the program that provides case management services to help secure funding for the costs related to non-medication health-care services (such as procedures, radiology needs and outpatient visits). They can be contacted directly at 1-800-532-5274.

Chronic Disease Fund <http://www.cdfund.org/default.html> Crohn's disease only

Modest Needs Foundation

<http://www.modestneeds.org/explore/mission>

- The Modest Needs Foundation provides one-time emergency grants to financially needy families or individuals.

Community Health Centers

<http://ask.hrsa.gov/pc/>

- If needed, free or low cost medical treatment can be found at community health centers, which are funded mostly by the federal government.

For information on ostomy supply assistance you may contact the following organizations:

- The Ostomy Group (530-432-9607)
 - Website: www.ostogroup.org Email: eme@ostogroup.org
- Friends of Ostomates Worldwide
 - Website: www.fowusa.org Email: info@fowusa.org
- United Ostomy Associations of America, Inc (UOAA) (800-826-0826)
 - Website: <http://www.uoaa.org/>
- Convatec Access Program (800-979-8716)
- Hollister (888-740-8999)
 - Website: www.hollister.com

If, after reviewing the information and you have further questions, you can contact the Crohn's & Colitis Foundation of America at 1.888.MY.GUT.PAIN (694-8872) or info@ccfa.org to get more information on medication and health insurance resource information.

III. Family and Medical Leave Act (FMLA)

What is the Family and Medical Leave Act?

Sometimes children with inflammatory bowel disease may have a severe course, with prolonged hospitalization, surgery, or school absence, or intermittent absences for things like Remicade infusions. During these periods, parents and other caretakers may need to leave work to care for their sick child. When this happens, you may be emotionally and financially stressed. You may even be afraid of losing your job. The Family & Medical Leave Act (FMLA) was passed in 1993 to help with such difficult situations.

- The FMLA was designed to help employees balance work and family responsibilities by allowing for reasonable unpaid leave for family or medical reasons. **The FMLA only applies to employers with 50 or more employees, and only to employees who have been employed for 12 months (1,250 hours).** Your state may have a law that applies to smaller employers. The FMLA is enforced by the U.S. Department of Labor Employment Standards Administration, Wage and Hour Division. Employers must post a notice explaining the rights and responsibilities under FMLA and may be fined if they fail to do so.
- FMLA provides up to 12 weeks of unpaid leave in any 12 month period. The 12 month period can be calendar year, fiscal year, or a rolling 12 month period. During the 12 weeks of leave, the employee cannot be fired. The 12 weeks of leave may be taken intermittently. However, if leave is taken for treatments, reasonable effort must be made to not disrupt the employer's operations.
- FMLA leave may be taken for many family and medical reasons, including:
 - the birth and care of a newborn child,
 - placement with the employee of child for adoption/foster care,
 - care of an immediate family member with a "serious health condition," or
 - the employee's own "serious health condition."
- A "serious health condition" is defined as:
 - A condition that results in at least 3 consecutive full calendar days of incapacity needing inpatient care;
 - A condition that requires continuing treatment by a health care provider and includes any period of incapacity lasting more than 3 consecutive days during which the individual needs treatment two or more times by a health care provider; or
 - A serious chronic health condition which continues over an extended period of time, requires repeated visits to a health care provider, and may involve occasional episodes of incapacity.
- If the need for leave is foreseeable (known in advance), thirty days' notice is needed to take FMLA leave. Otherwise, the employer must be notified as soon as practical of the need for leave. Employees must also give enough information so the employer can decide if FMLA applies to the request (such as hospitalization, pregnancy, unable to perform functions of the job, family member under continuing care of a provider).
- The employer is required to make premium payments on health insurance to maintain the employee's benefits while on leave. A 30 day grace period must be given before benefits may be cancelled. However, if the employee does not return to work for an appropriate reason, he/she may be required to reimburse the employer for those health insurance payments.

- Employees returning from FMLA leave must be reinstated to the same or equivalent job with the same pay, benefits, terms and conditions of employment.
- Employees may take, or employers may require employees to take, any accrued paid vacation, personal, family or medical/sick leave at the same time as FMLA leave (called substitution of paid leave).
- FMLA leave may be taken intermittently, a day here or there. You needn't use FMLA only for long-term absences.

How can your health care team help you with the family medical leave process?

In order to obtain FMLA leave, you must submit a written request to your employer. The health care provider will need to provide a medical certification of the need for absence. In most cases, all that is needed is a brief doctor's note establishing that you or a family member has a serious health condition, as defined above. In some cases, you may need to ask a member of the health care team to fill out a form for the company, or provide a more detailed letter of medical necessity. You are not required to provide medical records.

IV. Insurance Options

What are insurance options for patients with IBD?

Health insurance is necessary for patients with IBD. There are two kinds of group insurance plans: self-funded plans and fully-funded plans. Which kind of insurance plan you have might explain what your insurance is required to do under the law.

- Self-funded plans are plans under which the employer actually pays for the health care that is provided to the insured, and the insurer simply acts as a third-party administrator. Self-funded plans are governed solely by a federal law known as ERISA.
- Fully-funded plans are what we all commonly think of as insurance. With these plans, the employer purchases coverage from an insurer who pays the claims. Fully-funded plans are governed by state law.

Patients with IBD have several options for insurance:

- Insurance through a parent's policy - If a patient is a minor and is in school, he/she may be eligible to be insured under their parent's insurance. Under the new health reform law, the patient will be covered up to age 26 or until he becomes eligible for health insurance through an employer, whichever is earlier.
- Group insurance through an employer
- Individual insurance through public assistance (Medicaid, SCHIP)

What is COBRA?

Federal law mandates that patients be offered continuation of insurance at the patient's expense after a job ends or after a child is no longer under their parents' policy. This is called COBRA.

- If a patient decides to take COBRA after losing a job, they typically will have up to 18 months of coverage. This can be extended to 29 months if the patient has been found to be disabled by the Social Security Administration. If a patient decides to take COBRA after aging out of their parents' policy, they will have 36 months of COBRA coverage.
- The patient must pay the premium for the insurance plus a 2% administrative fee. Federal law requires employers to provide employees with COBRA information within 44 days of the qualifying event (end of the job or aging out of a parent's insurance). Patients then have a designated period of time (typically 60 days) to sign up for COBRA (called election). If the COBRA election is made more than 30 days after the qualifying event, the patient will have to pay the COBRA premium for all of those months so that COBRA coverage goes back to the date of the qualifying event.

What is "HIPAA eligibility"?

Federal law mandates that patients who are "HIPAA eligible" can buy health insurance that covers pre-existing conditions.

A patient is HIPAA eligible if they:

- have had 18 months of continuous insurance (the last day must have been in an employee based plan);
- have exhausted COBRA coverage;
- are not eligible for other insurance (i.e., group, Medicare, Medicaid);
- don't have health insurance;
- have not had a break in coverage of 63 days or more.

If you are HIPAA eligible, you must be offered a "guaranteed issue" policy. The "guaranteed issue" option differs from state to state. It may be the state's "high risk pool," which is a plan designed for people with pre-existing conditions. It may be each carrier's most popular plan, or a choice of a high and low-deductible plan. In some states, it is a plan offered by

Blue Cross. To find out what your state's "guaranteed issue" plan is for HIPAA eligible individuals, call your state's Insurance Department.

Insurance options for patients that are NOT HIPAA eligible:

- "High Risk Pool" for people with chronic illnesses - This is state run and usually very expensive.
- COBRA conversion policy (also called conversion policy) - This policy allows patients to change their group policy into an individual policy when leaving the group policy or when their COBRA expires. These policies are expensive and usually do not have complete coverage.
- "Mandated Issue/Guaranteed Issue" plans - Individual states require insurance companies to offer plans to those in need. These plans must be investigated on a state by state basis.

V. Letters of Medical Necessity

Letters of medical necessity are most often used to inform insurance companies of the need for a particular treatment. They can also inform schools or others of the need for accommodation based on an individual's health condition.

Preparing such documentation is often time consuming and requires the health care team's input, but health care providers are not paid for this work.

The following sample letters are designed to facilitate and simplify this process. These letters can be adapted by you or your medical team for your needs.

PLEASE NOTE THAT LETTERS OF MEDICAL NECESSITY MUST BE SIGNED BY A HEALTH CARE PROFESSIONAL, NOT BY THE PATIENT. The health care professional assumes responsibility for the precise content of the letter, which must be truthful and accurate. The sample letters below are examples only, drafted to assist and educate your medical team.

1. Letter in Support for a 504 Plan
- 2. Appeal of a medication that has been denied by insurance**
3. Appeal for off label use of medication
4. Appeal for wireless capsule endoscopy

Additional downloadable letters are available on the Crohn's and Colitis Foundation's Website in the professionals section (<http://www.cdfa.org/ccfaprof/>).

SAMPLE LETTER #1
(Letter in Support of a 504 Plan)

School Address

To Whom It May Concern:

NAME is a patient currently under my care. Due to **(her/his)** illness **(he/she)** is a candidate for school accommodations under section 504 of the Rehabilitation Act. **She/he** is substantially impaired in the major life activities of digestion, disposal of bodily waste, and eating.

This student has a form of Inflammatory Bowel Disease (“IBD”) called **(Crohn’s Disease/ ulcerative colitis)**. IBD is a chronic disease affecting the gastrointestinal system or GI tract. Ulcerative colitis affects the colon; Crohn’s Disease can affect any part of the digestive track, from the mouth to the anus.

The most common symptoms are diarrhea, abdominal and rectal pain and cramping, nausea, vomiting, fatigue, and arthritis-like joint pain. Although its cause is unknown, IBD involves the immune system and causes inflammation and ulceration of the lining of the intestines. The emotional and physical symptoms are interrelated in complex ways, and patients can experience flare-ups during times of emotional tension and stress.

Students with active IBD will need to use the bathroom several times a day – sometimes as many as 20 – often on a moment’s notice in order to avoid fecal incontinence. Incontinence still may occur, and students who suffer this symptom will need to be able to clean themselves and change clothes during the school day. IBD is a chronic illness that is cyclical; patients can face associated gastrointestinal symptoms in a recurrent pattern, with periods of symptom inactivity in between active flare-ups and complications. Symptoms may worsen in an unpredictable manner and conversely, may go into remission for varying lengths of time. Medications can help manage the discomfort and inflammation, but are not cures for IBD.

As a result this chronic condition, **NAME** requires accommodations which may include unlimited bathroom access, excused absences, and other accommodations.

Please call my office at **xxx-xxx-xxxx**, if you have any questions or concerns.

Sincerely,

Name
Contact Information

SAMPLE LETTER #2

Appeal of a medication that has been denied by insurance (example: adalimumab)

INSURER

RE: PATIENT
ID No.

Dear Sir or Madam:

I am writing to appeal the denial of coverage for the **Adalimumab** therapy for **PATIENT**. In the denial letter, INSURER found that the "request cannot be approved because this medication is considered investigational when used for the treatment of pediatric Crohn's Disease and is therefore a contract exclusion." However, there is extensive medical literature that proves that **adalimumab** (ADA) therapy is an effective treatment for Crohn's disease in patients who are allergic or intolerant to **infliximab**, which is currently conventionally used medication for Crohn's Disease.

In this case, ADA therapy is medically necessary. **PATIENT** has been tried on (specify treatment) in the past, with failure to control her/his disease. She/he has thus had to endure the symptoms of Crohn's Disease, such as abdominal pain and cramping, diarrhea, and fatigue – all symptoms that a child her age should not be required to live with. ADA therapy is necessary and she/he is an ideal candidate for such therapy. Thus, this appeal should be granted.

Numerous peer-reviewed articles demonstrate that patients with Crohn's Disease previously allergic or intolerant to infliximab actually respond favorably to the treatment of ADA, see Konstantinos A. Papadakis et al., Safety and Efficacy of Adalimumab (D2E7) in Crohn's Disease Patients with an Attenuated Response to Infliximab, 100 AM. J. GASTROENTEROLOGY 75 (2005). Other reliable studies found that ADA is well-tolerated and effective rescue therapy for moderate to severe pediatric CD patients previously treated with infliximab, see Rosh JR et al., Retrospective Evaluation of the Safety and Effect of Adalimumab Therapy (RESEAT) in Pediatric Crohn's Disease (2008)

I am enclosing a set of **PATIENT'S** medical records. These records show the following.

(State key medical findings and patient current condition)

The progression of his/her disease has prevented **PATIENT** from carrying on the normal daily activities of a X year old boy/girl, and the symptoms of her Crohn's Disease in combination with the constant hospital visits have taken both a physical and emotional toll.

In short, neither the diagnosis nor the severity of symptoms is in question, nor is there doubt that the alternative medical treatments have failed. **PATIENT'S** best chance for relief and the most appropriate course of treatment is the **adalimumab** therapy.

I request approval of **XX mg per week** of **adalimumab** therapy for **PATIENT**.

Please contact my office if you have additional questions.

Sincerely,

Name

Contact Information

Sample: Medication/Treatment; Off Label

SAMPLE LETTER #3
Appeal for coverage of off label medication

Date

INSURER

RE: Patient:
Treatment:
Provider:
Dates of Service: Ongoing

Dear Sir or Madam:

I am writing on behalf of **NAME** to appeal your non-coverage of **MEDICATION**.

Essentially, **INSURER's** rationale for denying coverage is that **MEDICATION** is not FDA approved for the treatment of **CONDITION**. This is not a credible rationale. First, I am enclosing copies of peer-reviewed medical literature that demonstrates that the use of **MEDICATION** is well-established for the treatment of **CONDITION**. Second, this patient has been tried and failed on all other treatment options, which have failed to control her **CONDITION**. Thus, your non-coverage decision should be reversed.

I. **MEDICATION CAN AND SHOULD BE USED TO TREAT DISEASE**

In 1982, the FDA issued a Drug bulletin addressing the prescribing of medication for "unlabeled" or off-label uses. The FDA itself states that the Food, Drug and Cosmetic Act "does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature".

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacture to the FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only.

FDA Drug Bulletin, Volume 12, Number 1, pages 4-5 (April 1982). If the FDA itself states that its' labeling is not intended to limit the prescribing of medications for off-label uses, then insurers should not be permitted to refuse coverage of off-label uses solely based on the fact that the use is off-label. Clearly, such a result would run contrary to the FDA's own intent regarding the effect of its labeling.

Many drugs, from 6MP to Asacol to Methotrexate, are used to treat Crohn's disease are used off-label, without FDA approval for this use. Yet, these drugs are covered by **INSURER** and every other insurance company or payment source including Medicaid and Medicare. Therefore, since **INSURER** has covered other medication not expressly FDA approved to treat Crohn's, the **INSURER** should continue to do so in the case of **PATIENT NAME**.

In fact, **MEDICATION** has been used to treat **DISEASE**. I enclose copies of medical journal articles that support its use. To summarize **[SUMMARIZE AND ATTACH COPIES]**.

II. **MEDICATION IS MEDICALLY NECESSARY IN THIS CASE**

My patient suffers from **DISEASE**. As demonstrated by the enclosed medical records [colonoscopy reports, barium studies, office notes indicating medications that were tried and failed, office notes showing weight loss], my patient requires aggressive treatment. She has been treated by each of the following, all of which have failed to alleviate her symptoms: _____

The **MEDICATION** I propose to use at this time may have a beneficial outcome. Unlike the other medications we have tried, **MEDICATION** may control her symptoms because _____

In each case, **PATIENT's** condition was not improved. However, when we tried a sample of **MEDICATION**, it was extremely effective.

Thus, it is my opinion, based on my **XX** years as a specialist in inflammatory bowel disease, that **MEDICATION** may be **PATIENT's** best and perhaps only chance for remission.

III. **Conclusion**

For all of these reasons, I urge you to reverse your non-coverage decision.

Sincerely,

Dr. X
Contact Information

SAMPLE LETTER 4
Insurance appeal for wireless capsule endoscopy procedure

Insurance Company

RE: PATIENT

DOB:

ID #

Pat Acct #

DATE

Dear Appeals Unit,

PATIENT was sent the **PRACTICE/HOSPITAL NAME** by his/her local gastroenterologist due to his/her severe **Crohn's Disease** symptoms. He/She came to this practice for a **second opinion** due to continued **severe diarrhea and abdominal pain**; his/her disease was believed to be confined to his/her **colon only**. A repeat colonoscopy performed here did confirm this, however his/her disease activity was mild and did not explain his/her severe, debilitating symptom as well as his/her **Vitamin B12 deficiency**. Review of his/her **RADIOLOGY PROCEDURE** by **CENTER'S Radiology** from an outside hospital showed no abnormalities.

Wireless capsule endoscopy is **recommended/advised** in cases where the diagnosis of **Crohn's disease** is known but it is necessary to determine the extent and severity of small bowel involvement and whether active inflammatory lesions exist in the setting of a functional bowel disorder. **Small bowel disease** was not detected despite other radiologic tests and again, **PATIENT** had significant **abdominal pain, elevated inflammatory markers and Vitamin B12 deficiency requiring repletion**.

A recent metanalysis focused on 11 prospective comparative studies comparing capsule endoscopy to other modalities for the diagnosis of established or suspected nonstricturing Crohn's disease. Capsule endoscopy was compared to ileoscopy, push enteroscopy, small bowel follow-through (SBFT), and small bowel MRI in a total of 228 patients. The yield for capsule endoscopy was significantly higher than for SBFT (63% versus 23%, respectively). Similarly, the yield for capsule endoscopy versus ileoscopy was 61% and 46%, whereas that for capsule endoscopy versus CT scan was 69% and 30% respectively. A subset analysis of patients with established but not suspected Crohn's disease showed that capsule endoscopy had a higher yield than other modalities.¹

Please reconsider your decision and allow me to use this diagnostic approach with **PATIENT**. If you have any further questions or concerns, please do not hesitate to contact my office.

Sincerely,

Name

Contact Information

¹ Leighton J, Legnani P, Seidman, EG. Role of capsule Endoscopy in Inflammatory Bowel Disease: Where We are and Where We are Going. *Inflamm Bowel Dis*. 2007;13(3):331-337.