

## Off-Label Drugs and Part D Coverage

### Off-Label Usage: Background

Physicians may, and often do, prescribe medications to treat conditions and diseases not expressly approved by the Federal Drug Administration (FDA). These are entirely legal prescribing practices and are often the standard of care for important drug therapies for chronic and progressive medical conditions, such as cancer.

Part D plan coverage of drugs for off-label use is prohibited unless evidence is produced that the off-label use is recognized and sanctioned by one of several specified drug reference compilations, called drug compendia. Drug compendia are collections of information about peer-reviewed medical literature and clinical trials that explain clinical uses of drugs that might go beyond FDA approved uses for drugs. None of these compendia are easily accessible to the public, and some are available only by expensive subscription. Citations to peer-reviewed medical literature, generally, will not suffice to reverse a coverage denial under Part D to establish coverage for an off-label use. An important exception is that peer-reviewed literature may be used to get approval for off-label uses of drugs to treat cancer in approved clinical trials.

### How You Can Help With Off-Label Denials

When your clients encounter such problems, they often have no way of knowing that an off-label usage may be the root cause, or what to do to get the medicines they need; they rarely have enough information at the pharmacy counter to understand why their pharmacists cannot fill their prescriptions. Rather, your client is likely to only be told that their Part D plan doesn't allow the prescription to be filled. All too often beneficiaries walk away perplexed and dismayed that they cannot get their prescription filled. Many will call their local trusted advocacy resource – you.

While most benefits counselors are not medical professionals, there are steps you can take to help your clients. Your clients will appreciate your help ascertaining that an off-label use is the cause of the problem and helping them decide what to do in order to get the medication the doctor wants them to have.

1. **Help your clients understand why their prescription couldn't be filled.** You can help your clients contact the plan to get specific information about the problem. You can also help them ask the pharmacist to interpret the electronic messages and explain the nature of the problem.

2. **Help your clients consider their options.** Think about the medical and legal professionals with whom you can partner in order to get your clients the medications their doctors want them to have. You'll probably want to consider many of these options simultaneously. Remember, your client's doctor can be a supportive ally for your client and you; the pharmacist may also offer assistance.

Here are some of their options:

#### **Option One: Is the Off-Label Use in a Drug Compendium?**

Find out if the off-label use is addressed in one of the drug compendia. You can ask your client's doctor for help getting the compendia. They are also available at medical libraries, medical schools or universities. Your client's physician may be able to help you understand the drug compendia and you might be able to partner with doctors to present any drug compendia evidence to the plan in order to reverse the off-label denial.

#### **Option Two: Can Your Client Get the Drug From a PAP?**

Find out whether a Patient Assistance Program (PAP) covers the drug for the off-label use. If a PAP will provide the drug, your client's condition will be treated and, as of 2011, the costs covered by the PAP count toward TrOOP. You can search for PAPs by drug at the [Medicare website](#) and you can download many PAP applications at [BenefitsCheckUp](#) (click on "Apply for Benefits").

#### **Option Three: Could the Drug Be Covered by Medicare Part A or B?**

You can explore whether your client's off-label drugs could be covered by Medicare Part A or Part B. This may seem quite drastic, but sometimes, the Medicare beneficiary must be hospitalized, and then the drug could be covered under Part A through the Medicare hospital benefit. Other off-label drugs are prescribed for cancer therapy or administered under the supervision of a physician and may be covered by Medicare Part B.

#### **Option Four: Appeal?**

Ask for an exception to the formulary; if it is denied, file an appeal. You will be working in tandem with your client's physician and can consider showing any medical evidence provided by the prescribing physician that no drug on a plan's formulary would be effective and/or that every drug on the formulary would produce adverse side effects. This evidence might include articles from respected medical journals and the physician's own research. Your local legal services or legal services for the elderly agency might be able to take cases involving Part D appeals.

### **When Off-Label Uses are Discovered after Prescriptions Are Filled**

Off-label uses are often discovered by plans *after* a prescription has been filled, upon audit or review, or because of a change in the dose or strength of a prescription.

When Part D plans discover that a prescription was filled off-label, they must send the affected enrollee an adverse coverage determination describing the non-coverage and warning the enrollee that the prescription will not be filled in the future due to the off-label prohibition. In describing withdrawing coverage for off-label prescriptions, it is very important to note that the Centers for Medicare & Medicaid Services (CMS) included the following directive to Part D plans: "We expect Part D plan sponsors to consider the enrollee's health situation, and continue to cover the drug to the extent it determines that doing so is necessary to avoid risk to the enrollee's health while providing for a transition to another form of treatment."

### **References**

See the Center for Medicare Advocacy, Inc. (CMA) September 16, 2010 [report](#) on Medicare coverage for off-label drug use.