



Layzer v. Leavitt Decision: What This Means for Your Off-Label Drug Appeal

The U.S. District Court of the Southern District of New York recently reached a decision in the case of *Layzer v. Leavitt* that could positively impact the outcome of your Medicare Part D off-label drug appeal.

Off-Label Part D Drug Usage before *Layzer v. Leavitt*

Before this decision, if you were signed up for a Part D of Medicare your Medicare drug plan would often refuse to pay for your drug if the U.S. Food and Drug Administration (FDA) label or at least one of three medical references called, “compendia” did not list the drug for your condition. Under Medicare rules, even if you appealed the denial of coverage for your drug and no alternative treatment existed, your appeal would be denied because the drugs were considered to be “off-label”.

***Layzer v. Leavitt* Decision**

In 2007, a lawsuit was filed in the U.S. District Court of the Southern District of New York. The lawsuit claimed that the plaintiff’s Medicare Part D plans should cover their prescriptions although the drugs were not specifically approved to treat these conditions by the FDA or in the compendia. On March 7, 2011, the Court ruled the plaintiffs’ drug plans should cover these medications.

The Court decided that federal law does not require Medicare Part D plans to refuse coverage for drugs for conditions that are absent from the FDA label or the compendium.

Possible Impact on Your Part D Appeal

The *Layzer* decision only applies in the New York counties of: New York (Manhattan), Bronx, Westchester, Putnam, Rockland, Orange, Dutchess, and Sullivan.

Even if you live outside these areas, the *Layzer* decision should strengthen your argument for an exception for coverage of your prescription medication as long as the drug is medically necessary and there is no covered alternative. This would be the case whether or not the drug’s use is found on FDA labeling or in the compendia.

Regardless of where you live, it is a good idea to attach the *Layzer* decision because it could be persuasive to the decision-maker of your appeal. As always you should also include all persuasive materials in your appeal, such as a letter of support from your prescribing doctor, medical literature that supports the prescription: an article from a peer reviewed journal like the New England Journal of Medicine or a clinical study from the drug’s manufacturer. Attached is a sample letter that you may want to use when you enclose the decision.



Sample Letter

Print on professional stationery, if possible

[Date]

[Address of party deciding appeal]

Re: Medicare Part D Drug Appeal
Beneficiary: **[Patient Name]**
Plan/Member ID:
Medicare Number:
Date of Birth:

Dear Sir/Madam:

I am writing to draw your attention to the recent U.S. District Court of the Southern District of New York decision in *Layzer v. Leavitt*. This case established that a drug need not be used for its U.S. Food and Drug Administration (FDA) approved use or a use set forth in the statutorily recognized compendia to be a “covered Part D drug” under a Medicare Part D drug plan.

In light of the favorable decision in *Layzer*, I ask that you provide an exception for coverage for **[insert medication]**, despite the fact that I am not using it for its FDA or compendia approved use, because, as I have separately established through **[if applicable the attached peer reviewed journal article, clinical study, etc.]**, the medication is medically necessary for my treatment and no covered alternative is appropriate. Thank you.

Sincerely,

[Your Name]

Attachments: *Layzer v. Leavitt* decision
[List any other attachments]