

*An Interview with Fiona Wilmot, MD, MPH, Medical Director of Policy, Pharmacy & Therapeutics, Blue Shield of California*

## Insurance coverage for rare cancers: the carrier's perspective

By Brian Klepper, PhD

**B**oard certified in internal medicine and with a Master's degree in public health, Fiona Wilmot's passion has long been "the delivery of the best care for the patient at the right time in the right setting," she says. Toward that end, Dr. Wilmot works with physicians and pharmacists to develop medical policies related to new technologies and therapeutics for Blue Shield of California (BSC). She also manages the Transplant Center of Excellence Program with a team of specialized nurse case managers. We spoke with her recently about seeking insurance coverage for treating rare cancers.

### **Community Oncology: How should physicians seek coverage for patients who need off-label drugs?**

Like many states, California has a mandate for coverage of off-label medication. A broadly written off-label statute states that the onus of responsibility is on the requesting physician to provide documentation such as published papers in support of his or her request. At BSC, we try to put the patient first and will generally perform research on our own to find the evidence needed to justify the request.

### **In other words, the medical director will help scour the literature to find evidence in support of the therapy?**

Sure. And we'll often ask our pharmacy team to help us, since they're knowledgeable about the research in this area. Another way a patient and

physician in California may have access to a cutting-edge treatment is through clinical trials. If a physician requests coverage for an experimental cancer therapy that does not meet the off-label drug statute, but there is a clinical trial being conducted and the patient can enroll in the trial, then the health plan is bound to cover some of the costs associated with that trial. BSC will search the National Cancer Institute and other databases to see whether there is an appropriate trial that the physician may have missed.

### **You want to follow an evidence-based protocol.**

Absolutely. Our technology and pharmacy and therapeutics committees recognize that advancement in science comes through research and data. We want patients to get access to the most appropriate evidence-based care and not miss the chance of better treatment simply because they are not aware of the options available.

### **How will transparency and pay-for-performance [P4P] affect these practice behaviors?**

For some of the major conditions like diabetes and heart disease, P4P has already had a significant effect. Because cancer care needs to be individualized for each disease and each patient, it's not as easy to envision and measure the effect of P4P. But using P4P to support evidence-based guidelines does show promise. In cancer there is a lack of head-to-head studies on different treatments. And the reality is that some

newer therapies may offer only incremental benefits over standard treatments. Some of the newer treatments are also very costly.

Even given these limitations, I do believe the data can be developed to make better decisions. As a health plan medical director, I'd like to see more discussions around developing meaningful comparisons of various treatments, and more public discourse on complex and charged issues such as allocation of resources and cost effectiveness.



**Fiona Wilmot, MD, MPH**

**So, in California at least, the off-label statute and the clinical trials mandate offer a way to move forward. If the physician satisfies his or her criteria, then you're obligated to provide funding for the therapy?**

I would say this is accurate. Clinicians, researchers, and patients should be aware that using medications outside of approved uses or specific sup-

porting data can unwittingly encourage poor science. We saw that with the use of bone marrow transplants for breast cancer. When there is a lack of evidence to support a treatment, I believe eligible patients ought to be enrolled in clinical trials so we can accrue the data necessary to make evidence-based decisions.

**This is an important argument. Let's say a physician wants a patient covered for a rare cancer treatment and there are very few data about the efficacy of that treatment. You're saying that if the health plan agrees to pay for a clinical trial with a protocol, then it's only fair that the physician and patient agree to adhere to that protocol.**

Right. In this instance, the patient's care would be approved under the clinical trials mandate, and the parameters around this care are clear. On the other hand, if a health plan approves a treatment outside those guidelines, then we're encouraging the delivery of an unproven treatment without any expecta-

tion that the outcome of that care will be documented to inform a physician's or patient's choices in the future. Additionally, for BSC the contract of coverage generally considers investigational or experimental care as not covered.

**You've tried to set up concrete guidelines so your decisions can't be interpreted as capricious, and you discourage unproven treatment practices in the medical community.**

Yes. By having stated coverage contracts, policies, and mandates, BSC strives to be completely transparent about our processes so that clinicians and patients understand the rationale for decisions.

**How do you deal with the fact that as the plan's representative you're often required to make decisions about funding unproven treatments in cases where the stakes are very high for the patient?**

The responsibilities can be enormous, which is why these decisions are never left up to an individual but pre-

sented to a committee of appropriate experts and voted upon. To the extent possible, it is critical for health plans to be completely transparent about their decision-making process.

**What's your most important message for oncologists whose patients are facing difficult or rare diagnoses?**

My advice is to do the homework. Know the relevant literature and clinical trials and follow the process for obtaining coverage from your particular plan. Most plans, including BSC, have this information available on their Web sites. Make the scientific case and be prepared to provide patient-specific data to support your request. In my experience, the plan is there to facilitate rather than obstruct care, and knowing the clinical issues as well as the plan's administrative process goes a long way toward achieving a satisfactory outcome.

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