Excerpt 18: Experimental - - Seize Their Weapons

Previous Excerpt 17 "Precedent -- Call in the Troops"

When a treatment is denied because it is "Experimental/Investigational," people assume that there is no way to challenge it. This ruling came down to Moses on the mountaintop. It is official. The treatment is inscribed on some sort of "Experimental List," yes?

Recently a patient said to me, "My surgery was denied because it is considered experimental."
"Considered experimental by whom?" I asked.
People—I am asking for a paradigm shift. Insurance company propaganda is very,very powerful and convincing. The initial approach is to make you feel comfortable, nurtured, and cared for.

Then, when you are in Big Medical Trouble, and the insurer does not want to pay for your treatment, the propanda switches. You are made to feel powerless, hysterical, and weak. Acme Insurance rolls our their full arsenal. We are official, we get to decide, we have the last word.

If you hack through all of the bureaucratic mumbo-jumbo, the message from your insurer is:

"We know what is best for you, and we hold divine power over your life and death."

What does "Experimental/Invesigational" mean? It means whatever Acme Insurance says it means. It means that they don't want to pay for it.

Purpose

Your insurer will deny your treatment with a letter. The denial letter from Acme Insurance is your Rosetta Stone, your gold mine—the foundation upon which you will build your appeal. Next, you will see how I confront their reason for denial in the Sample Appeal.

THIS TREATMENT IS NOT EXPERIMENTAL BY ACME'S OWN DEFINITION

In their denial letter, Acme states that this treatment is "Experimental," and they offer their definition. The one missing step? Acme does not offer any proof that cytoreductive surgery and HIPEC fits into or meets this definition in any way.

Let's examine Acme's own definition:

Experimental or Investigational Services: A Service is experimental or investigational for a Member's condition if any of the following statements apply to it as of the time the Service is or will be provided to the Member.

The Service:

FDA Approval

- cannot be legally marketed in the United States without the approval of the U.S.Food and Drug Administration (FDA) and such approval has not been granted;
- is the subject of a current new drug or new device application on file with the FDA.

The FDA approves drugs, medical equipment, and vaccines. The FDA does not deal with surgical

procedures.

The machine used to deliver the HIPEC is FDA-approved (510(k) number K993330). The drug that Dr. Sugarbaker uses for the HIPEC—mitomycin C—is FDA approved (ANDA numbers 064106, 064117, 064144, 064180).

Intraperitoneal administration of this drug is an "off-label" use. Physicians are invited to use drugs in ways not specified in the FDA approval to market; the FDA simply requires that the physician have a well-established clinical rationale for doing so. Surely it is clear by now that Dr. Sugarbaker, who has published 452 peer-reviewed medical journals on this topic, has his facts clearly in place.

Clinical Trial?

- is provided as part of a Phase I or Phase II clinical trial, as the experimental or reasearch arm of a Phase III clinical trial or in any other manner that is intended to evaluate the safety, toxicity or efficacy of the Service;is provided pursuant to a written protocol or other document that list an evaluation of the Service's safety, toxicity or efficacy as among its objectives;
- is subject to the approval or review of an Institutional Review Board (IRB) or other body that approves or reviews research concerning the safety, toxicity or efficacy of Services;
- is provided pursuant to informed consent documents that describe the Service as experimental or investigational or in other terms that indicate that the Service is being evaluated for its safety, toxicity or efficacy;

My treatment with Dr. Sugarbaker is not part of a clinical trial. It is not subject to approval by an IRB, and I was not given any document to notify me that it was part of a clinical trial. There is no "informed consent" associated with this treatment. It is not part of a clinical trial.

Prevailing opinion among experts

- is part of a prevailing opinion among experts as expressed in the published authoritative medical or scientific literature that (A) use of the Service should be substantially confined to research settings or (B) further research is necessary to determine the safety, toxicity or efficacy of the Service;

Surgical oncologists are the experts on disseminated abdominal cancers. In January 2006, surgical oncologists from all over the world met at the first International Symposium on Regional Cancer Therapies Snowmass, Colorado.

It was at this conference that the surgical oncologists began the process of standardizing their methods of patient selection, surgical approach, and delivery of HIPEC. By June of 2006, the experts had come together to make an official statement about this treatment:

(Esquivel J, Sticca R et al. Cytoreductive surgery and hyperthermic intraperitoneal chemotherapy in the management of surface malignancies: a consensus statement. Ann of Surg Oncol Jan 2007; 14(1):128-33.)

The paper covers "Materials and methods, Rigorous diagnostic work-up, Variables associated with increased chances of having a complete cytoreduction." The experts estimate the number of patients who could be helped by this treatment:

"In the United States an estimated 50,000 patients annually will present with or develop peritoneal carcinomatosis from primary colorectal cancer, gastric cancer, appendiceal cancer and ovarian cancer."

The following institutions participated in the Consensus Statement:

Akademiska University Hospital, Uppsala, Sweden

Altru Hospital, University of North Dakota, Grand Forks, ND, USA

Baltimore-Washington Medical

Baylor University Medical Center, Dallas, TX, USA

Beebe Medical/Christiana Care, Lewes, DE, USA

Charite Hospital Campus Mitte, Berlin, Germany

Creighton University Medical School, Omaha, NE, USA

Dekalb Medical Center, Decatur, GA, USA

Dorothy E. Schneider Cancer Center, San Mateo, CA, USA

Fairview University Medical Center, Minneapolis, MN, USA

First Surgical University Hospital, Belgrade, Serbia

H Lee Moffitt Cancer Center, Tampa, FL, USA

Helen F. Graham Cancer Center, Newark, DE, USA

Hospital General Universitario Gregorio Maranan, Madrid, Spain

Hospital San Jaime, Torrevieja, Spain

Hospital medica Sur, Tlalpan, Mexico

Hospital de San Pablo, Barcelona, Spain

Hospital Virgen de la Nieves, Granada, Spain

Hospital Torrecardenas, America, Spain

Institut Gustave Roussy, Villjuif, France

Instituto Nacional De Cancerlogia, Distrito Federal, Mexico

Johns Hopkins Hospital, Baltimore, MD, USA

Lousiana State University, Shreveport, LA, USA

Maine Medical Center, Portland, ME, USA

Mills-Peninsula Health Services, Burlingame, CA, USA

Medical School of Crete University Hospital, Herakleion, Greece

Miami Valley Hospital, Xenia, OH, USA

MD Anderson Espana, Madrid, Spain

Mercy Medical Center, Baltimore, MD, USA

National Cancer Institute of Milan, Milan, Italy

National Cancer Institute of USA, Bethesda, MD, USA

Netherlands Cancer Institute, Amsterdam, Holland

North Hampshire Hospital, Basinstoke, United Kingdom

Ospedale San Giovanni, Bellinzona, Switzerland

Ospedale S. Camillo-Forlanini, Rome, Italy

Policlinica San Jose, Vitoria, Spain

Roswell Park Cancer Center, Buffalo, NY, USA

St. Agnes Hospital, Baltimore, MD, USA

St. George Hospital, Sydney, Australia

St. Luke's Hospital, Bethlehem, PA, USA

Sharp Healthcare Hospital, San Diego, CA USA

Soroka University Medical Center, Beer Sheva, Israel

Surgical Departement Kantonsspital, St. Gallen, Switzerland

Surgical Oncology Associates, Newport News, VA, USA T

el-Aviv Sourasky Medical Center, Tel-Aviv, Israel

University of Iowa, Iowa City, IA, USA

University of Louisville, Louisville, KY, USA

University of Lyon, Lyon, France

University of Maryland, Baltimore, MD, USA

University of Medicine and Dentistry of New Jersey, Neward, NJ, USA

University of Pittsburgh Medical Center, Pittsburgh, PA, USA

University of Regensburg, Regensburg, Germany

University of Washington, Seattle, WA, USA

Wake Forest University, Winston-Salem, NC, USA

Walnut Creek Kaiser Permanente, Walnut Creek, CA USA

Walter Reed Army Medical Center, Washington, DC, USA

Washington Hospital Hospital Center, Washington, DC, USA

The overwhelming consensus among expert surgical oncologists is that complete cytoreduction—including peritonectomy procedures, and combined with heated intraperitoneal chemotherapy is now standard of care for disseminated abdominal cancers. This treatment should be offered to carefully selected patients whose disease is confined to the abdomen, and according to

Dr. Sugarbaker's Prior Surgery Score (PSS), and his Peritoneal Cancer Index (PCI).

When the insurer denies your treatment as "experimental"—where do you start? First, go to your benefits booklet, or the insurer's website, and find their definition of "Experimental/Investigational." If you can't find the definition in either place, call Acme Insurance, and tell them to fax it to you—today. If we don't give insurance companies time limits, they will never move fast enough for us.

Next, read the definition. Study it. Your are going to refute every part of their definition of "Experimental," and prove that your treatment is "Standard of Care."

Don't be afraid of insurance company definitions. What you say is just as valid as what they say.

FDA

When I ask people, "What does experimental mean?"—they always start by saying,"Not FDA-approved?"

Let's get one thing straight. Insurance companies deny treatments that are FDA approved every day of the week. And they routinely approve and offer treatments that are not FDA-approved.

In order to get over the FDA stumbling block, we need to understand two key facts about FDA approval:

1. **There is no such thing as FDA approval.**
2. **FDA only regulates drugs, food, and medical devices.**
3. Off-label use of drug and medical devices is perfectly acceptable.

There is no such thing as FDA Approval

What do I mean, "no such thing as FDA approval"? We imagine that the Food and Drug Administration is busy conducting all sorts of studies and experiments. When they are totally convinced that the drug or medical device is safe and effective, they issue an approval. Therefore, if a drug or medical device is not FDA-approved, it is not safe or effective, right?

Wrong. The FDA does not conduct tests or studies. It considers whatever documentation the manufacturer supplies to it. Think about that for a minute. Costmore Drug Company is submitting their new drug to the FDA. Costmore spent a gazillion dollars developing a new drug. They send their paperwork and documentation to the FDA. Do you think that any of Costmore Drug's own studies will be so negative as to spoil their case with the FDA?

The FDA reviews the articles, studies, and rationales that the drug or device manufacturer submits to them. If they feel that the drug or device is safe and effective, they issue a "Clearance to Market.
"There is no such thing as an "Approval." A Clearance to Market simply means that the drug company or device manufacturer is allowed to sell the drug or device to the public.

Once again—behold the power of words. "Approval" sounds like a

rock-solid stamp of approval. "Clearance to market" does not carry the same power.

Let's say that, in their denial letter, your insurer says, "This treatment is Experimental/Investigational. It is not FDA-approved."

FDA regulates food, drugs and medical devices

My requested treatment is a surgery with heated intraperitoneal chemotherapy (HIPEC). I don't know how many times I have heard doctors, patients, and insurers say, "The surgery is not FDA-approved, " or, "The HIPEC is not FDA-approved."

If you are going to argue your case, you need to know that FDA does not regulate treatments, surgeries, or procedures.

I would like to be a fly on the wall when you point out to your insurance company, "This procedure cannot be 'not-FDA-approved,' because the FDA doesn't regulate surgeries or procedures." This is exactly what I do in the Sample Appeal.

When you point out such blunders to Acme Insurance, it is very embarrassing. And embarrassing equals intimidating.

Off-label use of drugs and medical devices is perfectly acceptable

Let's say that your doctor prescribes an expensive drug, and the insurer denies it, saying, "Such-and-such a drug is Experimental for this Use" (or this condition, or whatever).

Just fire back with, "Such-and-such a drug is FDA-approved." Go to the FDA website, get the appropriate numbers, and supply them.

Then, go on to say, "What we are talking about is off-label use of an FDA-approved drug." Explain to them that physicians are welcome and invited by FDA to use approved drugs and devices for purposes other than those specified on the FDA. Clearance to Martket. Point out that the FDA requires that the physician keeps detailed clinical records of his off-label use, and your physician does this.

Knock out the FDA objection with one punch

In the appeal sample, I am requesting the heated intraperitoneal chemotherapy (HIPEC). This treatment involves a medical device (the heat pump), a drug (mitomycin C), and a procedure. Let's see how I deal with all three issues, wrap them up in a big bow, and lay them at the feet of Acme Insurance:

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Is it a clinical trial?

This business about clinical trials appears in most definitions of "Experimental/Investigational." In my sample definition , Acme Insurance devotes four paragraphs to it.

You know that your treatment is not a clinical trial. But you must address it.

Your insurer denied your treatment for one stated reason: It is experimental. So, you must address, answer, and debunk every word of their definition of "experimental."

Forgive me, but this clinical trials material is just silly—and easily disposed of.

If your treatment were a clinical trial, you would know it. They would have you fill out forms, sign disclaimers, and so on.

The most obvious sign that your treatment is a clinical trial? YOU DON'T HAVE TO PAY FOR IT. The treatment in most clinical trials is at cost to you.

I believe that insurers put all of this legalese about clinical trials into their definition of "experimental" just to make it longer and more intimidating. Here is how I dispose of it in the Sample Appeal:

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me that it was part of a clinical trial. There is no "informed consent" associated with this treatment. It is not part of a clinical trial.

Consensus of Experts

Here is the part of the sample definition that calls for a consensus of experts:

vii is part of a prevailing opinion among experts as expressed in the published authoritative medical or scientific literature that (A) use of the Service should be substantially confined to research settings or (B) further research is necessary to determine the safety, toxicity or efficacy of the Service;

"Experts"

"Published authoritative medical or scientific literature"

"Substantially confined to research settings"

"Safety, toxicity, efficacy"

They are trying to scare you with official-sounding words. Don't be afraid—you will engage in a little game of "dueling experts" with Acme Insurance, and you will win.

I will deal with Acme's experts later in the Sample Appeal. Here, as I hammer through their definition, I will first supply "prevailing opinion" that will completely blow theirs out of the water.

Who are your experts?

Know that Acme Insurance hasn't thought about who the experts are for your treatment. Think about it yourself, and get one jump ahead of them.

Let's say that you have colon cancer, and you have been denied and extremely expensive drug—Erbitux. Who are the experts on colon cancer, and where are there views and opinions to be found?

1. If you have a helpful in- or out-of-network doctor, ask him where you might find a consensus statement about your requested treatment.
2. Go Googling. Try phrases like "erbitux expert agreement," or "consensus erbitux oncologists."
3. Go to the NIH database of medical journal articles (http://www.ncbi.nlm.nih.gov/pmc?term=medical%20journal%20articles).
4. Search for "erbitux colon cancer," or some other likely phrase, and browse the abstracts. If you see a likely title, find the full-text article, and read it. Either the article itself may mention agreement among experts, or one of the articles found in the footnotes may contain some statement of consensus or agreement that this is an effective treatment for colon cancer.
5. Find the website for the professional group or association of medical oncologists. Search the website for news of consensus statements. Or, send them an email, and ask if such a consensus statement exists.

Once you have found some type of consensus or agreement among your professionals, do as I do on pages 101-102. Read and understand this statement, then quote the very best parts in your appeal.

I am fortunate enough to have in my files a consensus statement signed by the most respected surgical oncologists in the world for the treatment for which I appeal most often—cytoreductive surgery and HIPEC.

This statement lists the names of all signers. Plus, it lists the names of their institutions. In this case, the names of the institutions are more powerful than the names of the doctors.

Once again, we behold the power of names.

The appeal from which this section was taken was for an HMO; they denied this treatment as experimental. One of their very own HMO facilities appears on this list, with their own surgeon-expert endorsing the treatment. Huge gold nugget for the appeal.

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When it comes to consensus statements— the motto is the same as the motto for Insurance Warrior-ing in general. Never say never, search until you find what you need.

Don't worry about what you don't have. Take what you DO have, and use it to best advantage.

If the reason for their denial is "It's experimental"—you need to go after that word with everything you've got. When I began my own appeal process in 2005, I read and reread my HMOs definition of "experimental." I was delighted to discover how vague it was, how unfounded, how easy to shoot down.

Grab the word that your insurer has used to deny your treatment—be it "experimental," "out of network," or "not medically necessary." Then deconstruct it, and turn it to your advantage in your appeal.

Next Excerpt 19 "Not Medically Necessary: Use Their Weapons"
Return to main Insurance Warrior page.

To purchase Laurie’s book and CD, click here: http://theinsurancewarrior.com/thebookandthecd.html

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