

Virtual Mentor

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Health law

Experimental breast cancer treatments and health insurance coverage

by Lee Black, LLM

The only way that most people can afford medical treatment today is through health insurance. Aside from basic preventive care, and except for very wealthy people, the expense of care for major illnesses requires a third party to step in. Health insurance provides the benefit of paying for medical services that most people could otherwise not afford, but there are risks in assuming that having health insurance is the answer to all medical expenses.

Insurance contracts are complex documents, and most people do not read or fully understand them before signing away certain rights and remedies that may later be necessary to avoid either crippling debt or the inability to obtain proper care. When employers provide insurance coverage, the employee often does not automatically receive a copy of the health plan, within which there are usually exclusions of coverage. For example, many plans do not cover treatment for pre-existing illnesses and experimental or investigational treatments. Exclusions for experimental treatments are especially troublesome. The insured person, confident that all illnesses will be covered, may discover only after diagnosis that, while his or her illness is covered, all treatments for that illness are not.

Beginning in the 1990s breast cancer treatment, specifically high dose chemotherapy (HDC), peripheral stem cell rescue (PSCR) and autologous bone marrow transplant (ABMT), became a legal battleground for the fight over how and when the experimental or investigational exclusion clause could be applied. The problem usually arises when an insurer is asked to pre-authorize treatment and denies the request. The dispute ends up in court after the insured patient unsuccessfully appeals the decision to the insurance company, believing that the company was erroneous in its determination that the recommended treatment was experimental. Because of the expected devastating outcome if the patient does not obtain treatment and potentially unsatisfactory alternatives if insurance does not cover the sought-after therapy, these cases bring much emotion to the courtroom.

Insurance provisions for experimental treatment

The variety among insurance contract provisions relating to coverage of experimental treatments is astounding. They range from very sparse language which offers little insight into what an insurer considers experimental to very detailed provisions. In general, the less detailed the language, the better the outcome for the

patient who challenges a denial. This formula, however, is by no means foolproof. In some instances, even a definition of experimental that seems to allow for flexibility can be viewed by a court as sufficiently precise to preclude a challenge by the patient.

The following examples of contract language describing coverage for experimental treatment come from legal cases where the denial of coverage for breast cancer treatment was challenged.

1. “‘Experimental’ means those procedures and/or treatments which are not generally accepted by the medical community...” [1].
2. “[C]harges for treatment or service that (are) determined by the Plan Administrator to be experimental, investigational, unnecessary, and/or inappropriate for the condition, even if prescribed and/or ordered by a Doctor’ are excluded from coverage” [2].
3. “...Services...are Medically Necessary if they are...commonly and usually noted throughout the medical field as proper to treat the diagnosed condition, disease, Injury, or Illness...” [3].
4. “A drug, device or medical treatment or procedure is Experimental...if Reliable Evidence shows that the drug, device or medical treatment or procedure is the subject of ongoing Phase I, II, or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis...” [4].

The last example above is most specific as to what is considered experimental; the second and third are more vague and do not provide a definition of “experimental” that would aid an insured patient in determining what is covered. Herein lies the difficulty for HDC, PSCR and ABMT: especially in the 1990s, these medical procedures were given inconsistent treatment by judicial circuits.

In most cases, the terms of the insurance contract played a larger role in judicial decision making than medical opinion, a fact that had considerable consequence because parties generally interpret contracts in ways that are consistent with their own best interests. For insurance companies, best interests meant denial of a claim (although a poorly reasoned denial could more easily lead to liability). Patients, on the other hand, have an interest in treatment, so experimental procedures were quickly interpreted as “accepted by the medical community” as soon as they had received a few endorsements.

Experimental procedures in the courts

A wealth of cases examined experimental exclusion clauses in insurance contracts. The variety of bases for denial make it nearly impossible to apply one or even a few court decisions to the whole category. The cases discussed here have a few things in common: a patient and his or her physician believed that the proposed treatment was the best option for the patient, and the insurance company denied coverage on the

grounds that the treatment was experimental and therefore excluded or that other language in the contract exempted the treatment from coverage.

In *Lewis v. Trustmark Insurance Company*, the contract contained the least ambiguous definition of “experimental” in that it explicitly included clinical trials and studies as bases for exclusion. There was sufficient evidence to demonstrate that the proposed treatment fell into this definition, since numerous trials and studies were being performed on its safety and efficacy at the time [5]. With these facts before it, the court determined that the insurer was justified in denying coverage for HDC/PSCR.

At the opposite end of the ambiguity spectrum is *Reed v. Wal-Mart*. In this case the patient was diagnosed with stage II disease with cancer cells found in six lymph nodes. The insurer denied coverage, claiming it only covered HDC, PSCR or ABMT when 10 or more lymph nodes tested positive for malignancy; hence, the patient’s diagnosis meant the proposed treatment was experimental. The court found that the medical literature at the time, as well as the expert testimony at trial, did not establish sufficient justification for differentiating between six nodes and 10. Additionally, the experimental exception contract was deemed ambiguous, and unclear contract language is considered to be the fault of the drafter, in this case, the insurer. Strangely, some of the insurer’s expert witnesses testified that “experimental” had not been defined by the insurer, and these witnesses defined the term differently from each other. With the medical information available and the ambiguity in contract provisions, the court found for and granted judgment to the patient.

A final case with an unpredictable outcome is *Healthcare America Plans v. Bossemeyer*. The health plan language at issue in this case revolved around the ambiguous phrase “not generally accepted by the medical community” [6]. Both parties to the lawsuit submitted expert opinions, testimony and medical literature to support their respective arguments. Although the court upheld the insurer’s decision that the treatment was experimental, the evidence presented showed that there was significant opinion in medicine that the procedure, HDC/PSCR, was generally accepted. The fact that there were still trials to determine efficacy, especially between the proposed and other treatments, did not change the judgment of many physicians that the “experimental” option was the best available.

The court decided that because the contract gave the plan administrator the authority to use discretion over what was considered experimental, the phrase “not generally accepted by the medical community” was unambiguous. Even if the language was itself vague, the plan administrator’s discretionary authority meant that the contract did not meet the “arbitrary and capricious,” standard generally required for decisions in the patient’s favor. Since the administrator made decisions based on some information that the procedure was still experimental, the administrator was deemed justified in denying coverage.

Conclusion

Physicians can find it difficult to determine what is considered “experimental” and to plan patient care around the insurance uncertainties that they and their patients face. Clearly, there may be differences of opinion on what treatments are generally accepted and necessary, and insurance contracts have not always addressed or defined exclusions well enough to meet legal standards. Yet, even when courts find that health insurance contracts are sufficiently well-defined, patients and physicians still may not know what is covered and what is not.

Promising treatments that are still being investigated may be particularly helpful to certain patients. As the examples of high dose chemotherapy, autologous bone marrow transplant and peripheral stem cell recovery show, treatments that many physicians believe are appropriate, safe and efficacious may not meet the requirements of insurance contracts. Although these contracts may not intend to cheat patients out of necessary care, they are often perceived to do just that. Physicians should fight for what they believe is best for their patients. But it will not be easy. Once an insurer judges a treatment to be in the experimental, investigative or study stage, physicians will have an uphill battle. One thing that has not changed in the years since most of these court cases were decided is that the fundamental interests of physicians and insurers are at odds as often as not.

References

1. *Healthcare America Plans v Bossemeyer*, 953 F Supp 1176, 1179 (D Kan 1996).
2. *Reed v Wal-Mart*, 197 F Supp 883, 885-886 (ED Mich. 2002).
3. *Killian v Healthsource Provident Administrators*, 152 F3d 514, 516 (6th Cir 1998).
4. *Lewis v Trustmark Insurance Company*, US App 15746, 9 (4th Cir 1999)
5. *Lewis v Trustmark Insurance Company*, 11-12.
6. *Healthcare America Plans*, 1179.

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