

# Blue Cross relents, funds cancer study

by Linda Everett

Amid mounting lawsuits from their subscribers, the Blue Cross and Blue Shield Association (BCBS) announced in mid-November that 15 of its 70-plus member plans will participate in a \$10 million round of clinical trials to study the effectiveness of autologous bone marrow transplant procedures as treatment for breast cancer. About 1,200 women are expected to participate in the trials, which will be sponsored by the National Cancer Institute, starting in the first quarter of 1991. Blue Cross and Blue Shield Plans will pay for the treatment of 300 to 600 women subscribers who have breast cancer.

Since 1987, the Johns Hopkins Oncology Center has proven autologous bone marrow transplants to be 90% effective in saving the lives of women with advanced metastatic breast cancer who otherwise would have died. Johns Hopkins is just one of ten centers which has successfully used these transplants in fighting advanced breast cancer. The procedure involves removing a portion of the patient's bone marrow, rather than the marrow of a genetically matched donor. The marrow is purged of any cancer cells and stored while the patient undergoes four days of chemotherapy so potent that it is as lethal to healthy bone marrow as it is to the targeted malignant cancer cells.

There is a direct relationship between the intensity of the chemotherapy given and the rate of response. If the marrow is not removed before such intense chemotherapy, the patient is rendered unable to produce blood—which is as bad as the original disease being fought. Once the high-dose, continuous infusion of chemotherapy is complete, the marrow is returned to the patient intravenously. Typically, institutions charge about \$120,000 for the treatment. In 30% of 140,000 people who are diagnosed with breast cancer every year, the disease spreads elsewhere in the body, usually to the brain, the lungs, or the kidneys. For patients at this stage of cancer, there is no other therapy available.

Reportedly, 70% of the nation's other insurers already cover this procedure. Despite the fact that a Johns Hopkins study released a year ago reported that there were no treatment-related deaths in the marrow rescue program, the majority of Blue Cross and Blue Shield Plans still claim that the therapy is experimental or investigational, and therefore cannot be covered. BCBS has admitted that one reason for

starting the clinical trials, is that patients covered by BCBS plans who are denied coverage for this treatment, often sue BCBS and win.

What the insurer did not say, was that its announcement to start this "unprecedented" plan to magnanimously fund clinical trials, was timed to hit the nation's press the same day that a major test case against BCBS for refusing to cover exactly this kind of therapy went to federal court in Baltimore. In that case, BCBS refused to pay for autologous bone marrow transplants for two young mothers with Stage-IV cancer. At least eight other similar cases are pending against BCBS in Maryland alone.

## Randomized testing: 'immoral and unethical'

The National Cancer Institute (NCI) says it planned the randomized testing of marrow transplant therapy which BCBS wants, because it is scientifically necessary. But Dr. Mark Lippman, the former head of NCI's breast cancer programs and a world expert in the field, recently testified in the Baltimore case that "it is immoral and unethical to have randomized testing" of this therapy, because it is the *only* therapy that can save these patients. Results from the Blue Cross-NCI collaborative effort won't be in for three years, and so scores of BCBS subscribers denied the therapy will die in the meantime. Already there are suspicions that NCI and/or BCBS will insist on lengthy randomized trials of autologous marrow transplant therapy for each of a vast spectrum of deadly diseases for which it has proven effective and where no other therapy exists, including various stages of Hodgkin's disease, non-Hodgkin's lymphoma, leukemia, and other killer cancers, including ovarian and lung cancers (most of which BCBS does not cover). As a Johns Hopkins representative suggested, the principle involved in all marrow rescue programs is the same, no matter which disease is involved. To demand separate trials on the effectiveness in each case, serves only to stall bringing this valuable treatment on line in the population.

NCI normally oversees clinical trials at their designated cooperative groups of hospitals and cancer centers. This time BCBS calls the shots, and it appears that the insurer has bypassed some known leaders in this area of research, like Johns Hopkins. BCBS says it will choose trial sites on the basis of quality, volume, and outcome. But one attorney involved and familiar with scores of suits against BCBS says that it is more likely that the insurer will choose centers that are geographically located where a handful of BCBS plans which *already* cover this life-saving therapy operate.

Another element adding to subscribers' skepticism is the conflict of interest apparent here as well. The health policy expert BCBS asked to evaluate clinical data on autologous marrow transplant therapy is Dr. David Eddy of Duke University—the same Dr. Eddy whom BCBS hired last summer to testify on behalf of the insurer when BCBS was sued for refusing to cover this "experimental" therapy.