STATES REPORT REIMBURSEMENT CONSTRAINTS

An increasing number of states are reporting problems with legislative or insurer-sponsored health policy revisions that constrain physicians' ability to provide state-of-the-art cancer treatment. In particular, recent actions are targeting non-FDA approved uses of drugs as "experimental" and, thus, ineligible for reimbursement or, at the very least, subject to informed consent requirements.

Illinois

Illinois amended the Medical Practice Act of 1987 to "include within its definition of 'experimental procedures' the use or administration of a drug for a purpose that may not have been approved by the U.S. Food and Drug Administration." Illinois-based physicians did not become aware of the proposed amendment until it was on the Governor's desk awaiting his signature. As a result, and because of other state-level reimbursement concerns, such as CPT coding, concerned oncologists have formed the Illinois Medical Oncology Society (IMOS), according to pro tem president, James Wade, M.D., Cancer Care Institute, Decatur (IL) Memorial Hospital.

The bill came about when it was discovered that residents at Cook County Hospital in Chicago were prescribing Dilantin for an experimental use without informed consent or even the knowledge of patients. As a result, "the amendment to the Medical Practice Act was drawn up to protect all people in the state from the experimental use of drugs that may be FDA approved, but not for a specific indication," Wade says.

Fortunately, lobbying efforts by oncologists, pharmacists, pharmaceutical companies, and ACCC Executive Director, Lee Mortenson, were successful in convincing the governor to veto the amendment.

Missouri

Blue Cross and Blue Shield of Kansas City (MO) has adopted new reimbursement policies for such procedures as bone marrow transplantation, the use of experimental drugs, and the prescribing of approved drugs for off-label indications, according to Robert Belt, M.D., Principal Investigator for the Kansas City Clinical Oncology Program.

"At a meeting in Chicago, a number of regional Blue Cross and Blue Shield plans hammered out the conditions under which they will or will not pay for certain procedures," Belt says. "I know they came up with a list of approved bone marrow transplants and a list for infusional chemotherapy. I've tried to obtain a copy of the lists and haven't been able to."

According to Belt, the involved Blue Cross and Blue Shield plans have indicated that "they are not going to pay for anything that is determined to be investigational," based on their definition of investigational.

Texas

On July 7, the Medicare intermediary in Texas, Blue Cross and Blue Shield, issued a Part B Newsletter that restricts coverage for the drugs Interferon and Methotrexate to FDA-approved indications.

"This is the first attempt I have seen in the state of Texas by Medicare to limit payment to specific indications," says Joseph Bailes, M.D., an oncologist in McAllen, TX, and a member of the clinical practice committee of the American Society of Clinical Oncology.

The change in coverage policy will effectively deny reimbursement for Interferon when used to treat renal cell carcinoma or bladder cancer. Coverage for Methotrexate excludes seven indications endorsed by the U.S. Pharmacopeia since 1988, including leukemia, multiple myeloma, sarcomas, cancers of the ovary, bladder, and prostate, and renal cell carcinoma. Phillip Periman, M.D., President and Medical Director of the Don and Sybil Harrington Cancer Center, Amarillo, says that Medicare recently denied reimbursement for the treatment of transitional cell carcinoma of the bladder with Methotrexate which, he explains, is "an essential component of M-VAC treatment of the disease."

Periman is also concerned about the effect of such a policy on rare forms of cancer. He points out that small cell carcinoma of the bladder and carcinoma of the bowel duct are so rare, and there is so little clinical data available, that no antineoplastic agents are currently labeled as effective treatment for those diseases. "Does such a ruling mean that patients with those diseases are not eligible for any reimbursable treatment?"

Indiana

Blue Cross and Blue Shield of Indiana has demanded that the Indiana Oncology-Hematology Consultants, Indianapolis, refund more than $30,000 in payments it received for treating a patient with Interferon for refractory multiple myeloma. They have informed the Blues that they will not refund the payments, because the treatment is not "experimental." At *Oncology Issues* deadline, the case was still pending.

Minnesota

Blue Cross and Blue Shield of Minnesota issued a Medical Policy Update in June which states that any drug used for any indication not approved by the FDA is investigational, according to Patrick Flynn, M.D., Principal Investigator for the Metro-Minneapolis CCOP. In addition, the policy update states that it will only cover portable infusion pumps when they are used for heparin infusion, analgesia, or the treatment of metastatic colon cancer, carinoid tumors or liver cancer. "They're excluding coverage for all other types of ambulatory chemotherapy infusion," Flynn says.

Minnesota-based oncologists are having severe difficulties with Medicare denials for off-label indications, according to Flynn, particularly for Leucovorin and 5FU for the treatment of metastatic colon cancer. "What is really frustrating is that we don't always get the same answer about coverage," he says. "It varies depending on who the carrier is for the patient's supplemental insurance."

And, as if differences in payment policies among federal, commercial, and prepaid plans weren't confusing enough, there are two Medicare intermediaries in Minnesota—Blue Cross and Blue Shield and Traveler's—and they also differ on what they will and will not cover. "A patient of mine with metastatic colon cancer received pre-approval from Blue Cross and Blue Shield for continuous 5FU infusion. After seven months of treatment, Traveler's became his intermediary and tried to deny payment for all previous therapy, saying it was medically unnecessary," Flynn says. "I can't tell you how frustrating that is for the patient." ■