Medicare to pay for methotrexate

By STEVE ALBERT
Review Staff Writer

After years of controversy, Florida Medicare officials have decided to offer limited reimbursement to rheumatologists dispensing intramuscular methotrexate injections to patients with severe rheumatoid arthritis.

Florida physicians will join a handful of rheumatologists nationwide who have approval to use the drug, still not sanctioned by the U.S. Food and Drug Administration.

The ruling, which many physicians view as an important reversal of an obsolete Medicare policy, hinges on a little-used regulation and a letter-writing campaign by Florida physicians.

Medicare’s surrender was not unconditional, however.

Federal payments still will come only after case-by-case reviews by Medicare’s Florida carrier, Blue Cross-Blue Shield of Jacksonville.

Medicare guidelines do not allow reimbursement for drugs not approved by the FDA. As a treatment for rheumatoid arthritis, methotrexate is classified as investigational.

“Our decision was based on input from rheumatologists around the state,” said Richard Dever, MD, vice president for medical affairs at Blue Cross.

“We’ve never reimbursed for methotrexate before,” said Dever. “This is definitely an exception.”

Florida doctors say the drug, an immunosuppressant approved by the FDA as an anticancer and psoriasis treatment, has won widespread acceptance in the past few years as a rheumatoid arthritis therapy when gold, penicillamine or plauennil have failed.

Until the FDA announces broader approval, Medicare in Florida will cover methotrexate injection therapy only when physicians document that patients have been unresponsive to conventional therapy and cannot tolerate the methotrexate orally because of gastrointestinal side effects.

Physicians estimate only 5 percent of all rheumatoid arthritis cases are treated with methotrexate injections, and only 1 percent of those cases would qualify for Medicare coverage.

Because there has never been Medicare coverage for an oral, self-administered prescription drug, reimbursement for methotrexate in the oral form is not an issue. The oral therapy almost always is used before injections are attempted.

The injections cost $20 per 30-milligram dose and $12 per 25-milligrams, Gaylis said. The shots are given four times monthly.

In a New England Journal of Medicine article, researchers said methotrexate cannot be considered a cure for rheumatoid arthritis, but it can significantly ease the pain and swelling.

The Medicare exception wouldn’t have been granted if Florida doctors hadn’t lined up in support of the drug.

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Arthritis drug gets Medicare nod

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Sixty of Florida’s 91 rheumatologists responded when Norman Gaylis, MD, of Parkway Regional Medical Center’s Center for Arthritis and Rheumatic Diseases in North Miami Beach, asked them to take a stand. Most use the drug already.

“At the grassroots level, they are using it because they believe in it,” Gaylis said.

“Many of these doctors are using it despite the fact they may be putting themselves at risk,” he said.

When physicians use a drug in ways not approved by the drug maker or the government, they bear all the liability if a patient has an adverse reaction, Gaylis said.

The letters streamed in.

Peter Wunsh, MD, of Lake Worth: “Methotrexate will become a major treatment modality for rheumatoid arthritis, and it is unfair to deny reimbursement... If we, as physicians can relieve the pain, suffering, deformity and disability of rheumatoid arthritis by using this medication, we should be allowed to administer the drug with the full confidence of reimbursement.”

South Miami MDs Jerry Rosenbaum, Michael Weitz and Peter McCroskey: “We must have over 50 patients in our practice on methotrexate.”

Louis Ricca, MD, of St. Petersburg: “...Any rheumatologist who does not use methotrexate in selected instances is not practicing progressive, modern, state-of-the-art rheumatology.”

Angel F. Vidal, MD, of Hialeah: “It has proven quite safe and extremely efficacious, and has become one of our best tools to combat this serious illness.”

Rheumatologists have insisted that the help methotrexate offers to severe or advancing rheumatoid arthritis patients outweighs the usefulness of waiting years for clinical drug trials as a prelude to Medicare approval.

In the meantime, doctors say, many handicapped patients are hard-pressed to buy the drug. Methotrexate supporters recently discovered a loophole that, in the absence of FDA approval, allows Medicare to extend coverage if the drug is generally accepted by physicians in a geographic area.

The same loophole has been used by physicians in other parts of the country. HCFA officials say untested drugs have been approved for reimbursement in specific geographic areas when medical and technical support for monitoring was available.

Because questions remain about the intent of Medicare rules, Dever has asked HCFA’s national medical advisory group to address the issue.

Methotrexate manufacturer Lederle Laboratories of Wayne, N.J., did not seek FDA approval for rheumatoid arthritis until June. The company said it has been monitoring private studies around the country for several years.

“You just can’t pop drugs on the market,” said Lederle spokesman Bob Schwadron. “This is a powerful drug that has to be thoroughly tested.”

Last bills go out for malpractice fund

By STEVE ROTHMAN
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About 3,700 Florida physicians and surgeons have received bills totalling $8.8 million covering the “last assessment” they will ever have to pay into the state’s Patient Compensation Fund to cover medical malpractice claims for the year 1982-1983.

But more than two-thirds of those doctors won’t have to pay a dime because their PCF assessments are covered by the Florida Medical Malpractice Joint Underwriters Association.

The state-created association sold assessment protection insurance during in 1982.

In May, physicians received bills totalling $9 million for an assessment of 102 percent of the original fee paid for coverage, said PCF administrative manager Catherine Sims said.

“There is a possibility of hardship for those physicians who didn’t purchase assessment insurance protection,” Sims said. If a physician has a true hardship, the fund will work out a payment schedule for them, she said.

The August assessment will cause doctors or their insurance carriers to pay up to 200 percent of the original PCF membership fee for the $10 million worth of excess medical malpractice coverage, she said.

This amounts to twice the $18,825 Dade and Broward county surgeons, anesthesiologists, gynecologists and other high risk specialists paid for such coverage that year.

The same specialists in Palm Beach County paid $11,296.

Dade and Broward low-risk physicians, such as general practitioners, will be assessed up to 200 percent of the $2,261 they paid, she said.

Palm Beach County low-risk physicians will pay fees based on the $1,357 charged for excess medical malpractice insurance coverage.

In 1982, only physicians were members of the PCF, Sims said. All the hospital members had dropped out.