



Norman Gaylis, MD, holds vial of controversial arthritis treatment.

Review photo by Bill Cooke

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, hinged 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 wide acceptance in the past few years as a rheumatoid arthritis therapy when gold, penicillamine or plaquenil 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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The ambulatory records of patients admitted to an acute care facility with several specific diagnoses automatically would be reviewed.

The diagnoses were selected because they have significant potential for revealing possible inappropriate management of outpatient care, officials said.

Fifteen diagnoses have been selected for discussion purposes but the list is expected to be changed during the federal review process.

An example would be a hospital admission for a ruptured appendix. While the treatment prior to admission might be entirely appropriate,

State weighs reimbursement

By CRESTON NELSON
Review Staff Writer

Florida soon may become the first state in the nation to reimburse hospitals on a diagnosis-related group basis for work compensation cases.

A three-member panel studying the switch from charge-based reimbursement was to meet last week in Tallahassee to determine the percentile of charges on which DRG rates would be based.



State Insurance Commissioner Bill Gunter, Miami attorney Richard Sicking and Southern Bell corporate medical director James Byrd, MD, serve on the panel that earlier this year approved the DRG reimbursement plan in concept.

Panel chairman Sicking said Florida only in recent years imposed a fee schedule on hospitals. Before that there was no limit on hospital charges, he said.

The workers compensation program presently reimburses hospitals based on charges, up to a statewide limit of \$151 per day plus "bed charges" plus generally unlimited amounts for ancillary services.

Hospitals, like other health care providers, are prohibited by law from collecting any difference from

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 Wunsch, 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 McCroskery: "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**
Review Staff Writer

About 3,700 Florida physicians and surgeons have received bills totalling \$8.8 million covering the "last assessment" they will ever have to pay 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.

sibilities.
"I'm on cloud 9," said. "I'm extremely happy to see the Cleveland Clinic district out from all in Florida they can't see. It's wonderful for the community."

All participating hospitals would be on the roll, Weaver said.

Patients requiring care at a district hospital intermediaries might be the clinic, which would reimburse the hospital.

Bonne Solomon

Gov. Bob Graham edged three incumbents on the North Palm Beach District Board.

The terms of county Commissioner Mapleton, Sharo Amos Bonner expired but Graham did not reappoint them until they continued their meetings in the interim.

Mapleton, 52, past chairman of the board since 1977, is principal black, is principal of Lauderdale.

Solomon, 40, Sheriff Nick Nava on the board since

North

North Ridge County in Oakland Park American Medical one of the national companies.

The 395-bed academy was purchased for \$75 million from founding founders M. and Modesto Mo

The two physicians American Hospital AMI in June, giving Florida units.