

Medicare Pay Situation Makes Planning Difficult

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Doubt and low morale are rampant in many practices in light of the uncertainty surrounding Medicare physician payment rates this year.

While members of Congress averted a 10% cut in the Medicare physician fee schedule, replacing it instead with a 0.5% increase, that increase is mandated only until midyear. Congress must act again by

July to keep an ever-deeper cut from going through.

The uncertainty is making it difficult for physicians to plan ahead even a year at a time, and is causing some to avoid taking on new Medicare patients.

Dr. Fred Ralston Jr., a general internist in Fayetteville, Tenn., and chair of the health and public policy committee of the American College of Physicians, rarely sees new patients in his established practice. However, given the recent lack of ac-

tion to reform payments, he has decided to stop accepting new Medicare patients in his practice.

Although his eight-physician primary care group won't drop any current patients, he said that taking on new Medicare patients, with their complex problems, amounts to "charity." "The reimbursement for those with multiple problems is very limited compared to several less complex younger patients who could be seen in the same [amount of] time," Dr. Ralston said.

Other physicians made the decision not to take new Medicare patients years ago. Dr. Andrew Merritt, a family physician in Marcellus, N.Y., closed his practice to Medicare patients about 5 years ago because of the uncertainty of the payment situation.

As a result, Medicare now makes up less than 20% of his practice, and the current payment situation hasn't had a large impact on his bottom line. But if payments were to worsen significantly, he might be forced to consider other changes to his practice, such as limiting patients to presenting one problem at each appointment.

The fiscal situation makes rational long-term financial planning almost impossible, said Dr. Ralston. He estimates that in a

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practice in which almost two-thirds of the revenue goes to overhead, a 10% cut would mean about 30% off the bottom line.

For example, Dr. Ralston's practice purchased an electronic medical record system because they

thought it would help them to provide better care to patients. But it was probably a foolish economic decision, he said, because they don't know whether they will have the revenue to pay for it.

"It continues the uncertainty of what the practice income will be," said Dr. Yul Ejnes, an internist in Cranston, R.I., and a member of the ACP Board of Regents. "We're all small businesses."

Practices can't do anything aggressive in terms of practice development and growth, he said. For example, it's difficult for a practice that needs to recruit new physicians to guarantee a competitive pay package when they can't estimate how much money will be coming in, he said.

It also affects the morale of physicians, especially those who care for the chronically ill elderly population, Dr. Ejnes said.

Dr. Robert Lebow, a solo internist and geriatrician in Southbridge, Mass., finds the Medicare payment situation to be demoralizing. Dr. Lebow, who still accepts new Medicare patients, said the flat payments are an added insult to the enormous paperwork burden and constant questioning of orders by payers. Dr. Lebow estimates that he spends an extra 1-2 hours a day completing paperwork for insurance companies.

And he is concerned about what this will mean to the future of primary care. Even as some payments for cognitive services have increased slightly in recent years, many physicians feel that it's too little, too late, he said.

Dr. Lebow, who is 63 years old, worries that there will be no one to replace him when he retires. "There are very few young people in primary care," he said. ■

BRIEF SUMMARY OF PRESCRIBING INFORMATION



For topical use only Rx only

INDICATIONS AND USAGE

Extina® (ketoconazole) Foam, 2% is indicated for the topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older. Safety and efficacy of Extina Foam for treatment of fungal infections have not been established.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Contact Sensitization

Extina Foam may result in contact sensitization, including photoallergenicity. [See Adverse Reactions, Dermal Safety Studies]

Flammable Contents

The contents of Extina Foam include alcohol and propane/butane, which are flammable. Avoid fire, flame and/or smoking during and immediately following application. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C).

Systemic Effects

Hepatitis has been seen with orally administered ketoconazole (1:10,000 reported incidence). Lowered testosterone and ACTH-induced corticosteroid serum levels have been seen with high doses of orally administered ketoconazole. These effects have not been seen with topical ketoconazole.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse reactions that appear to be related to drug use and for approximating rates.

The safety data presented in Table 1 (below) reflect exposure to Extina Foam in 672 subjects, 12 years and older with seborrheic dermatitis. Subjects

applied Extina Foam or vehicle foam twice daily for 4 weeks to affected areas on the face, scalp, and/or chest. Adverse reactions occurring in >1% of subjects are presented in Table 1.

Table 1: Adverse Reactions Reported by >1% Subjects in Clinical Trials

Adverse Reactions	Extina Foam N = 672 n (%)	Vehicle Foam N = 497 n (%)
Subjects with an Adverse Reaction	188 (28%)	122 (25%)
Application site burning	67 (10%)	49 (10%)
Application site reaction	41 (6%)	24 (5%)

Application site reactions that were reported in ≤1% of subjects were dryness, erythema, irritation, paresthesia, pruritus, rash and warmth.

Dermal Safety Studies

In a photoallergenicity study, 9 of 53 subjects (17%) had reactions during the challenge period at both the irradiated and non-irradiated sites treated with Extina Foam. Extina Foam may cause contact sensitization.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects, Pregnancy Category C:

Ketoconazole has been shown to be teratogenic (syndactyly and oligodactyly) in the rat when given orally in the diet at 80 mg/kg/day (4.8 times the maximum expected human topical dose based on a mg/m² comparison, assuming 100% absorption from 8 g of foam). However, these effects may be partly related to maternal toxicity, which was also observed at this dose level. [See Pharmacokinetics]

No reproductive studies in animals have been performed with Extina Foam. There are no adequate and well-controlled studies of Extina Foam in pregnant women.

Extina Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether Extina Foam administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted in

human milk, caution should be exercised when Extina Foam is administered to women who are breastfeeding.

Pediatric Use

The safety and effectiveness of Extina Foam in pediatric patients less than 12 years of age have not been established.

Of the 672 subjects treated with Extina Foam in the clinical trials, 44 (7%) were from 12 to 17 years of age. [See Clinical Studies]

Geriatric Use

Of the 672 subjects treated with Extina Foam in the clinical trials, 107 (16%) were 65 years and over.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic or photo-carcinogenic potential of Extina Foam.

In oral carcinogenicity studies in mice (18-months) and rats (24-months) at dose levels of 5, 20 and 80 mg/kg/day ketoconazole was not carcinogenic. The high dose in these studies was approximately 2.4 to 4.8 times the expected topical dose in humans based on a mg/m² comparison. In a bacterial reverse mutation assay, ketoconazole did not express any mutagenic potential. In three *in vivo* assays (sister chromatid exchange in humans, dominant lethal and micronucleus tests in mice), ketoconazole did not exhibit any genotoxic potential.

At oral dose levels of 75 mg/kg/day (4.5 times the expected topical human dose in mg/m²), ketoconazole impaired reproductive performance and fertility when administered to male rats (increased abnormal sperm, decreased sperm mobility and decreased pregnancy in mated females).

Manufactured for Stiefel Laboratories, Inc. Coral Gables, FL 33134 USA

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U.S. Patent Pending

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