

Physicians Advise CMS on Pay for Performance

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WASHINGTON — The Centers for Medicare and Medicaid Services is jumping on the pay-for-performance bandwagon, but members of a physician advisory group warned CMS officials to be careful how they go about it.

“I’m only hoping that you’ll structure this so that the quality indicators will be that you’ve [performed] certain process-

es, not necessarily the outcome” of them,” said Laura B. Powers, M.D., a Knoxville, Tenn. neurologist and member of the Practicing Physicians Advisory Council.

For example, outcomes are not good in terminal patients, Dr. Powers told this newspaper. “What outcome are they going to measure with an amyotrophic lateral sclerosis patient who is definitely going to die?” she said.

Instead, Medicare should assess whether

the physician has followed appropriate standards of care for terminal patients.

Trent Haywood, M.D., acting deputy chief medical officer at the agency, said CMS has debated that very issue. “There has been a lot of discussion about what is the right thing [to measure]. We’ve always said that we think it’s both,” he said. “We definitely want process measures ... and the current financial structure is also easier for measuring processes, because that’s the way we traditionally pay people.”

However, he added, “our goal is toward getting some evidence of outcomes. The process measures we normally collect are always related to outcomes.”

Council member Peter Grimm, D.O., a radiation oncologist in Seattle, said he believes that outcomes are the most important thing to measure. “You have to have outcomes as the bottom line,” said Dr. Grimm, who runs a quality assurance business involving 300 physicians. “I don’t care how people get there. I just care that they get there.”

In his testimony to the council, Dr. Haywood outlined the various steps Medicare is taking to introduce pay for performance into physician reimbursement, including demonstration projects with hospitals and group practices. But Dr. Grimm still was not satisfied.

“One thing I didn’t hear is how you verify this [performance] data,” he said. “You have to have a third party evaluate it.”

Geraldine O’Shea, D.O., an internist in Jackson, Calif., said that she is concerned about the impact of pay for performance on the doctor-patient relationship.

“Could it discourage physicians from caring for noncompliant patients?” she asked. “And how do these programs ensure the most up-to-date guidelines are being used? How can we get this out to know that this is the benchmark we’re going to be measured at?”

There are different ways to address patient compliance, Dr. Haywood said. “If

you lean more heavily on process measures, that takes care of part of that problem, because those process measures look at whether you prescribed something or did something. But because we still want to look at outcomes measurement, we also talk about ways in which you allow that patient to be excluded. You can have documentation saying, ‘Provided counseling and patient refused.’”

Council member Barbara McAneny, M.D., an oncologist in Albuquerque, N.M., said she was concerned about the expense of the computer system that would be required for physicians to keep track of their outcomes data.

“The electronic medical record (EMR) that our practice purchased some years ago is now completely inadequate because it’s not searchable for tumor stage, size, or treatment,” she said. “So I have been shopping for an EMR.”

“The most recent quote I got for the EMR that can provide the functions I want ... for a practice of nine physicians, they want \$400,000,” she continued.

“Well, my Medicare drug money just went away, the physician fee schedule is going down, and the [Medicare payment formula] is going to nail us 30% over the next 6 years. Where am I going to find \$400,000 to put in an EMR that I can search and find all stage II breast cancer patients, and see whether they got their chemotherapy, and how they are doing, and by the way, how many of them are on Vioxx, and I have got to call them up and get them off it? All these kinds of issues are really going to have to be addressed.”

Dr. Haywood agreed. “You’re articulating some of the barriers we face as we continue to try to work through this process,” he said. “We’ve started to map out strategies to address some of those issues.” Right now the agency is discussing the idea of certifying EMR systems to help physicians decide which ones to purchase, he noted.

and a one-year study of once weekly FOSAMAX® (alendronate sodium) 70 mg the rates of discontinuation of therapy due to any clinical adverse experience were 2.7% for FOSAMAX 10 mg/day vs. 10.5% for placebo, and 6.4% for once weekly FOSAMAX 70 mg vs. 8.6% for placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in 2% of patients treated with either FOSAMAX or placebo are presented in the following table.

	Two-year Study		One-year Study	
	FOSAMAX 10 mg/day % (n=148)	Placebo % (n=95)	Once Weekly FOSAMAX 70 mg % (n=109)	Placebo % (n=58)
Gastrointestinal				
acid regurgitation	4.1	3.2	0.0	0.0
flatulence	4.1	1.1	0.0	0.0
gastroesophageal reflux disease	0.7	3.2	2.8	0.0
dyspepsia	3.4	0.0	2.8	1.7
diarrhea	1.4	1.1	2.8	0.0
abdominal pain	2.1	1.1	0.9	3.4
nausea	2.1	0.0	0.0	0.0

Prevention of osteoporosis in postmenopausal women

The safety of FOSAMAX tablets 5 mg/day in postmenopausal women 40-60 years of age has been evaluated in three double-blind, placebo-controlled studies involving over 1,400 patients randomized to receive FOSAMAX for either two or three years. In these studies the overall safety profiles of FOSAMAX 5 mg/day and placebo were similar. Discontinuation of therapy due to any clinical adverse experience occurred in 7.5% of 642 patients treated with FOSAMAX 5 mg/day and 5.7% of 648 patients treated with placebo.

In a one-year, double-blind, multicenter study, the overall safety and tolerability profiles of once weekly FOSAMAX 35 mg and FOSAMAX 5 mg daily were similar.

The adverse experiences from these studies considered by the investigators as possibly, probably, or definitely drug related in 1% of patients treated with either once weekly FOSAMAX 35 mg, FOSAMAX 5 mg/day or placebo are presented in the following table.

	Two/Three-Year Studies		One-Year Study	
	FOSAMAX 5 mg/day % (n=642)	Placebo % (n=648)	FOSAMAX 5 mg/day % (n=351)	Once Weekly FOSAMAX 35 mg % (n=352)
Gastrointestinal				
dyspepsia	1.9	1.4	2.2	1.7
abdominal pain	1.7	3.4	4.2	2.2
acid regurgitation	1.4	2.5	4.2	4.7
nausea	1.4	1.4	1.4	1.4
diarrhea	1.1	1.7	1.1	0.6
constipation	0.9	0.5	1.7	0.3
abdominal distention	0.2	0.3	1.4	1.1
Musculoskeletal				
musculoskeletal (bone, muscle or joint) pain	0.8	0.9	1.9	2.2

Concomitant use with estrogen/hormone replacement therapy

In two studies (of one and two years' duration) of postmenopausal osteoporotic women (total: n=853), the safety and tolerability profile of combined treatment with FOSAMAX 10 mg once daily and estrogen ± progestin (n=354) was consistent with those of the individual treatments.

Treatment of glucocorticoid-induced osteoporosis

In two, one-year, placebo-controlled, double-blind, multicenter studies in patients receiving glucocorticoid treatment, the overall safety and tolerability profiles of FOSAMAX 5 and 10 mg/day were generally similar to that of placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in 1% of patients treated with either FOSAMAX 10 mg/day (n=157), FOSAMAX 5 mg/day (n=161), or placebo (n=159), respectively, were: **Gastrointestinal:** abdominal pain (3.2%; 1.9%; 0.0%), acid regurgitation (2.5%; 1.9%; 1.3%), constipation (1.3%; 0.6%; 0.0%), melena (1.3%; 0.0%; 0.0%), nausea (0.6%; 1.2%; 0.6%), diarrhea (0.0%; 0.0%; 1.3%); **Nervous System/Psychiatric:** headache (0.6%; 0.0%; 1.3%).

The overall safety and tolerability profile in the glucocorticoid-induced osteoporosis population that continued therapy for the second year of the studies (FOSAMAX: n=147) was consistent with that observed in the first year.

Paget's disease of bone

In clinical studies (osteoporosis and Paget's disease), adverse experiences reported in 175 patients taking FOSAMAX 40 mg/day for 3-12 months were similar to those in postmenopausal women treated with FOSAMAX 10 mg/day. However, there was an apparent increased incidence of upper gastrointestinal adverse experiences in patients taking FOSAMAX 40 mg/day (17.7% FOSAMAX vs. 10.2% placebo). One case of esophagitis and two cases of gastritis resulted in discontinuation of treatment.

Additionally, musculoskeletal (bone, muscle or joint) pain, which has been described in patients with Paget's disease treated with other bisphosphonates, was considered by the investigators as possibly, probably, or definitely drug related in approximately 6% of patients treated with FOSAMAX 40 mg/day versus approximately 1% of patients treated with placebo, but rarely resulted in discontinuation of therapy.

Laboratory Test Findings

In double-blind, multicenter, controlled studies, asymptomatic, mild, and transient decreases in serum calcium and phosphate were observed in approximately 18% and 10%, respectively, of patients taking FOSAMAX versus approximately 12% and 3% of those taking placebo. However, the incidences of decreases in serum calcium to <8.0 mg/dL (2.0 mM) and serum phosphate to <2.0 mg/dL (0.65 mM) were similar in both treatment groups.

Post-Marketing Experience

The following adverse reactions have been reported in post-marketing use:
Body as a Whole: hypersensitivity reactions including urticaria and rarely angioedema. Transient symptoms of myalgia, malaise and rarely, fever have been reported with FOSAMAX, typically in association with initiation of treatment. Rarely, symptomatic hypocalcemia has occurred, generally in association with predisposing conditions.

Gastrointestinal: esophagitis, esophageal erosions, esophageal ulcers, rarely esophageal stricture or perforation, and oropharyngeal ulceration. Gastric or duodenal ulcers, some severe and with complications have also been reported (see WARNINGS, PRECAUTIONS, Information for Patients, and DOSAGE AND ADMINISTRATION).

Skin: rash (occasionally with photosensitivity), pruritus, rarely severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Special Senses: rarely uveitis, rarely scleritis.

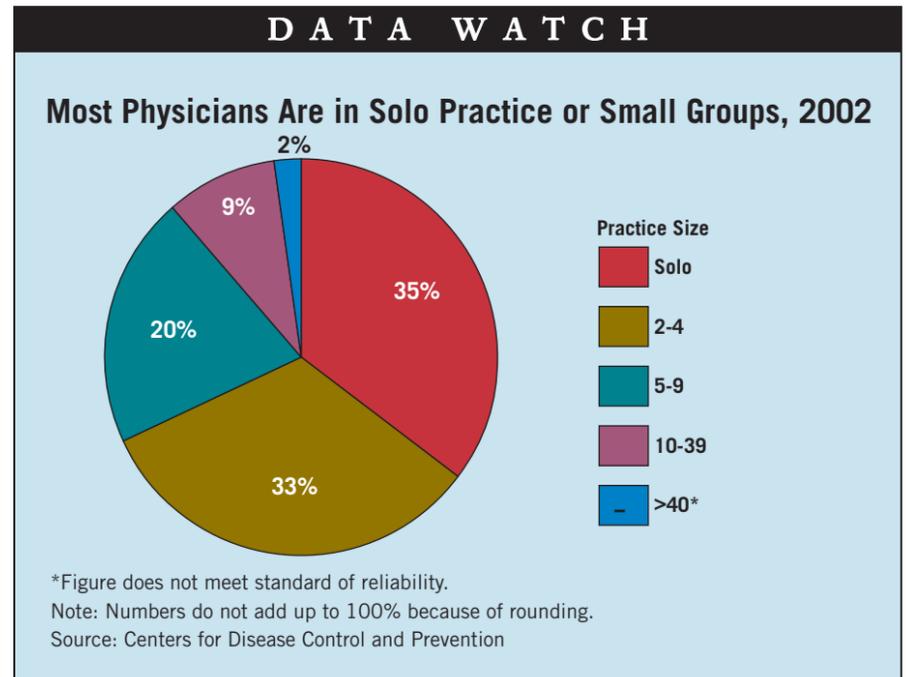
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