

Humana, Medicare Tops in Payer Performance

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Humana and Medicare were rated highest when it came to paying quickly and being easy to work with, based on an assessment of performance by one of the nation's largest physician revenue management companies. The performance data was tabulated and made public by AthenaHealth, a Waretown, Mass.-based company that man-

ages \$2 billion in revenues for 7,000 physicians, nurses, and other health care providers in 33 states. In explaining why the company decided to make the data available free of charge, Jeremy Delinsky, director of process innovation at AthenaHealth, said, "We were a little skittish about making it public, but we found the story was too compelling to sit on." And, physicians who know more about their insurers will have more contracting leverage and a better chance to

improve their bottom line, Mr. Delinsky said. The company assessed 5 million "charge lines" worth of claims data from the fourth quarter of 2005. To be a part of the ranking, national payers had to have at least 10,000 "charge lines," or line items, and regional payers at least 3,000. Insurers were ranked according to an overall index that gave the most weight to financial performance. That performance included days in accounts receivable, percentage of claims paid and closed on the first pass, and percentage of charges transferred to the patient. The index also included an administrative measure encompassing the claims denial rate, the percentage requiring a phone call to clarify a response from the insurer, and the percentage of claims lost. Finally, a small amount of weight was given to the difficulty of working by the payer's rules. Nationally, Humana ranked number one, followed by Medicare, United Health Group, Aetna, Cigna, Champus, and Wellpoint. According to AthenaHealth, Aetna denies claims twice as often as Humana, and the reasons are so unclear that 17% of claims need follow-up calls. Wellpoint tended to take the longest to pay, and more than any other payer, the company aggressively shifts responsibility to physicians to get payment from the patient. For all payers, claims stay in accounts receivable for an average of 38 days. On the regional level, there was a wide variation in performance. In the northeast, for example, BlueCross BlueShield of

Pennsylvania/Independence BlueCross was the top-ranked plan, followed by Tufts Health Plan and Fallon Health Plan. In the west, PacifiCare was first, followed by Medicare B in Texas and United Health Group. The largest regional payers mostly provided clear reasons for denials, rarely shifted the responsibility to physicians to secure payment, and paid most claims upon first submission and within 30 days. Regional payers appeared to be more efficient and perhaps even more powerful than the national insurers, he said. AthenaHealth did not assess payers' relative reimbursement rates because it would not be legal to publicize those rates, Mr. Delinsky said. However, he suggested that physicians could use his company's rankings to negotiate for a higher fee if the payer is hard to work with, or potentially accept a lower payment rate if the insurer pays more quickly and imposes less of an administrative burden. The insurance industry did not respond directly to the rankings, but America's Health Insurance Plans, a national trade association, completed a study recently showing that 98% of claims submitted electronically are processed within a month of receipt. The study, based on aggregated data from 25 million claims processed by a sample of 26 health insurers, found that 75% of all claims are submitted electronically, up from 24% in 1995. The rankings are posted at www.athenapayerview.com.

Reports of hypoglycemia in patients treated with rosiglitazone added to maximum metformin therapy were more frequent than in patients treated with rosiglitazone or metformin monotherapies. In double-blind studies, symptomatic hypoglycemia was reported by 3.0% of patients receiving rosiglitazone added to maximum doses of metformin, by 1.3% of patients receiving metformin monotherapy, by 0.6% of patients receiving rosiglitazone as monotherapy, and by 0.2% of patients receiving placebo. Overall, anemia and edema were generally mild to moderate in severity and usually did not require discontinuation of treatment with rosiglitazone. In the initial therapy double-blind trial, the incidence of edema was 6% on AVANDAMET compared to 7% on rosiglitazone and 3% on metformin. Edema was reported in 4.8% of patients receiving rosiglitazone compared to 1.3% on placebo, 2.2% on metformin monotherapy, and 4.4% on rosiglitazone added to maximum doses of metformin. Overall, the types of adverse experiences reported when rosiglitazone was added to metformin were similar to those during monotherapy with rosiglitazone. In the initial therapy double-blind trial, the incidence of anemia was 4% in patients treated with AVANDAMET compared to either rosiglitazone (2%) or metformin (0%). Reports of anemia (7.1%) were greater in patients treated with rosiglitazone added to metformin compared to monotherapy with rosiglitazone. Lower pre-treatment hemoglobin/hematocrit levels in patients enrolled in the metformin combination second-line therapy clinical trials may have contributed to the higher reporting rate of anemia in these studies (see ADVERSE REACTIONS, Laboratory Abnormalities, Hematologic). In 26-week double-blind, fixed-dose studies, edema was reported with higher frequency in the rosiglitazone plus insulin combination trials (insulin, 5.4%; and rosiglitazone in combination with insulin, 14.7%). Reports of new-onset or exacerbation of congestive heart failure occurred at rates of 1% for insulin alone, and 2% (4 mg) and 3% (8 mg) for insulin in combination with rosiglitazone. Similarly, an increased incidence of heart failure has also been observed when rosiglitazone was added to a sulfonylurea or to a sulfonylurea plus metformin. There were too few events to confirm a dose relationship; however, the incidence of heart failure appeared higher with rosiglitazone 8 mg daily. (See WARNINGS, Rosiglitazone maleate, Cardiac Failure and Other Cardiac Effects.) In postmarketing experience in patients receiving thiazolidinedione therapy, serious adverse events with or without a fatal outcome, potentially related to volume expansion (e.g., congestive heart failure, pulmonary edema, and pleural effusions) have been reported. (See WARNINGS, Cardiac Failure and Other Cardiac Effects.) In postmarketing experience with rosiglitazone maleate, angioedema and urticaria have been reported rarely. Postmarketing reports of new onset or worsening diabetic macular edema with decreased visual acuity have also been received (see PRECAUTIONS, Rosiglitazone maleate, Macular Edema).

(See also GLUCOPHAGE prescribing information, ADVERSE REACTIONS). **Pediatric:** Rosiglitazone has been evaluated for safety in a single, active-controlled trial of pediatric patients with type 2 diabetes in which 99 were treated with rosiglitazone and 101 were treated with metformin. In this study, one case of diabetic ketoacidosis was reported in the metformin group. In addition, there were 3 patients in the rosiglitazone group who had FPG of ~300 mg/dL, 2+ ketonuria, and an elevated anion gap. The incidence and type of adverse events reported in ≥5% of patients for each treatment group are shown below.

Adverse Events Reported by ≥5% of Patients in a Double-Blind, Active-Controlled, Clinical Trial With Rosiglitazone or Metformin as Monotherapy in Pediatric Patients

	AVANDIA N = 99	Metformin N = 101
Preferred Term	%	%
Headache	17.2	13.9
Influenza	7.1	5.9
Upper Respiratory Tract Infection	6.1	5.9
Cough	6.1	5.0
Hyperglycemia	8.1	6.9
Dizziness	5.1	2.0
Back Pain	5.1	1.0
Nausea	4.0	10.9
Hypoglycemia	4.0	5.0
Nasopharyngitis	3.0	11.9
Vomiting	3.0	8.9
Abdominal Pain	3.0	6.9
Pharyngolaryngeal pain	2.0	5.0
Diarrhea	1.0	12.9
Sinusitis	1.0	5.0
Dysmenorrhea	0	6.9

Laboratory Abnormalities: Hematologic: Decreases in mean hemoglobin and hematocrit occurred in a dose-related fashion in adult patients treated with rosiglitazone maleate (mean decreases in individual studies up to 1.0 gram/dL hemoglobin and up to 3.3% hematocrit). The time course and magnitude of decreases were similar in patients treated with a combination of rosiglitazone and other hypoglycemic agents or rosiglitazone monotherapy. Pre-treatment levels of hemoglobin and hematocrit were lower in patients in metformin combination studies and may have contributed to the higher reporting rate of anemia. In a single study in pediatric patients, decreases in hemoglobin and hematocrit (mean decreases of 0.29 g/dL and 0.95%, respectively) were reported with rosiglitazone. White blood cell counts also decreased slightly in adult patients treated with rosiglitazone. Decreases in hematologic parameters may be related to increased plasma volume observed with rosiglitazone treatment. In controlled clinical trials of metformin hydrochloride of 29 weeks' duration, a decrease to subnormal levels of previously normal serum vitamin B₁₂ levels, without clinical manifestations, was observed in approximately 7% of patients. Such a decrease, possibly due to interference with B₁₂ absorption from the B₁₂-intrinsic factor complex, is, however, very rarely associated with anemia and appears to be rapidly reversible with discontinuation of metformin or vitamin B₁₂ supplementation. **Lipids:** Changes in serum lipids have been observed following treatment with rosiglitazone maleate in adults (see CLINICAL STUDIES in complete prescribing information). Small changes in serum lipid parameters were reported in children treated with rosiglitazone for 24 weeks. **Serum Transaminase Levels:** In clinical studies in 4,598 patients treated with rosiglitazone maleate encompassing approximately 3,600 patient years of exposure, there was no evidence of drug-induced hepatotoxicity or elevated ALT levels. In controlled trials, 0.2% of patients treated with rosiglitazone maleate had reversible elevations in ALT >3X the upper limit of normal compared to 0.2% on placebo and 0.5% on active comparators. Hyperbilirubinemia was found in 0.3% of patients treated with rosiglitazone compared with 0.9% treated with placebo and 1% in patients treated with active comparators. In the clinical program including long-term, open-label experience, the rate per 100 patient years of exposure of ALT increase to >3X the upper limit of normal was 0.35 for patients treated with rosiglitazone maleate, 0.59 for placebo-treated patients, and 0.78 for patients treated with active comparator agents. In pre-approval clinical trials, there were no cases of idiosyncratic drug reactions leading to hepatic failure. In postmarketing experience with rosiglitazone maleate, reports of hepatic enzyme elevations 3 or more times the upper limit of normal and hepatitis have been received (see PRECAUTIONS, Hepatic Effects).

OVERDOSAGE: Rosiglitazone maleate: Limited data are available with regard to overdosage in humans. In clinical studies in volunteers, rosiglitazone has been administered at single oral doses of up to 20 mg and was well tolerated. In the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient's clinical status. **Metformin hydrochloride:** Hypoglycemia has not been seen with ingestion of up to 85 grams of metformin hydrochloride, although lactic acidosis has occurred in such circumstances (see WARNINGS). Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated metformin from patients in whom metformin overdosage is suspected.

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FDA Renews Crackdown on Unapproved Prescription Drugs

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The Food and Drug Administration announced that it is renewing efforts to ensure that all drugs currently sold by prescription either go through its formal approval process or be taken off the market. There are many reasons why unapproved products are on the market, said Dr. Steven Galson, director of the FDA's Center for Drug Evaluation and Research, at a press briefing sponsored by the agency. Most were marketed before passage of the 1962 Food, Drug, and Cosmetic Act, which required formal proof of safety and efficacy. Or their makers may simply have begun selling the products without seeking the agency's approval, he said, noting that the FDA will issue a new drug code (NDC) number for a product even if it was never approved. In very few cases, the products are grandfathered in under existing laws. Many of the unapproved drugs are listed in the Physicians' Desk Reference. Some are advertised in medical journals. Those initially flagged for attention include products that are potentially hazardous, lack evidence of effectiveness, or appear to be fraudulent.

If the manufacturers don't seek approval, they will be subject to enforcement, Dr. Galson said. But in most cases, the FDA will not remove a drug shown to have some medical utility. Examples include some manufacturers' levothyroxine and phenobarbital products. "While we want to ensure continued patient access to necessary treatments, as a physician I feel strongly that patients expect and deserve all their prescription medicines to be FDA approved," said Dr. Andrew C. von Eschenbach, acting FDA commissioner, in a statement. The agency estimates that less than 2% of prescription drugs have not received its imprimatur. That still means potentially thousands of products that aren't approved. Many are cough and cold preparations that include pheniramine maleate and dexbrompheniramine maleate, or single-ingredient narcotics such as codeine phosphate and oxycodone HCl. Sedatives like chloral hydrate are also unapproved. Physicians, pharmacists, and patients can go to the FDA's Web site (www.accessdata.fda.gov/scripts/cder/drugsatfda) to determine if a drug is approved. The database includes only approved medications, so unapproved products will not be listed.