

# Experiment Begins With Online Insurance Portal

*Beginning this month, physicians in Ohio and New Jersey will use one site for all private payers.*

BY MARY ELLEN SCHNEIDER

In November, physicians in Ohio and New Jersey will begin to test a single, online portal through which they can access health insurance eligibility and benefits information for most of their privately insured patients.

Physicians and their staffs in those states will have access to data on copayments, deductibles, in-network and out-of-network coverage, and the status of claims from multiple plans in one place. They will also be able to submit referrals, preauthorization requests, and claims under a test project spearheaded nationally by America's Health Insurance Plans and the Blue Cross and Blue Shield Association.

Ultimately, the initiative will be rolled out across the country, AHIP President and CEO Karen Ignagni said during a press conference.

"It's a step that will ultimately transform our system to one that takes advantage of technology to the benefits of clinicians and their patients," she said.

The changes are significant, Ms. Ig-

agni said, and are akin to what the banks did when they first allowed consumers to withdraw money from any ATM around the world.

The initiative is expected to decrease hassles for physicians and significantly reduce costs for both physicians and health plans. Ms. Ignagni estimated that the entire health system could see savings of hundreds of billions of dollars once these administrative simplification tools are available around the country, based on estimates of savings automating administrative tasks and implementing consistent business practices.

The insurers' announcement comes as Congress debates comprehensive health reform, including tighter regulation of the insurance industry. Ms. Ignagni said that AHIP has been exploring projects to simplify insurance administration over the last year and has kept the Obama administration and congressional leaders apprised of their progress. Some simplifications are already part of health reform proposals circulating in Congress, she said.

"As Congress considers health care re-

form, I think all of us believe that it's critical that we bend the cost curve," Ms. Ignagni said. "Most policy makers understand that health reform that doesn't address the cost of care will fail."

She added that projects like the ones in Ohio and New Jersey have "great potential to slow the growth in the cost of



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MS. IGNAGNI

care and contribute to savings needed nationally for reform."

Although this type of Web-based tool has been possible for years, the standards for sharing information across multiple health plans were only recently completed, Ms. Ignagni said. With the standards in place, the state-level pilot projects will focus on making sure the Web portal is user friendly for physicians, and on learning which functions are most helpful.

The project will begin with physicians

and will be extended to hospitals later, according to AHIP.

The initiative was praised by physician organizations that are working on the project in Ohio, where eight health plans representing 91% of privately insured residents will participate in the Web portal. Mark Jarvis, senior director of practice economics at the Ohio State Medical Association, said that the ability to access insurance information through one online source will make administrative tasks easier, faster, and more accurate.

This type of tool is critical, he said, because it allows the physician's staff to let patients know up front what their coverage is and how much they will end up paying. "If you can have that conversation before the encounter, the transaction works much better and [is] less confusing than if you're trying to chase it after."

Mr. Jarvis estimated that the average physician spends 3-4 hours a week on administrative dealings with insurance companies, whereas his or her staff spends another 58 hours on insurance-related administration in a given week. Creating a one-stop shop for insurance information is a great "first step" to try to reduce the administrative burden on physician practices, he said. ■

Bosentan was teratogenic in rats given oral doses two times the maximum recommended human dose [MRHD] (on a mg/m<sup>2</sup> basis). In an embryo-fetal toxicity study in rats, bosentan showed dose-dependent teratogenic effects, including malformations of the head, mouth, face and large blood vessels. Bosentan increased stillbirths and pup mortality at oral doses 2 and 10 times the MRHD (on a mg/m<sup>2</sup> basis). Although birth defects were not observed in rabbits given oral doses of up to the equivalent of 10.5 g/day in a 70 kg person, plasma concentrations of bosentan in rabbits were lower than those reached in the rat. The similarity of malformations induced by bosentan and those observed in endothelin-1 knockout mice and in animals treated with other endothelin receptor antagonists indicates that teratogenicity is a class effect of these drugs [see **Nonclinical Toxicology**].

#### Nursing Mothers

It is not known whether Tracleer is excreted into human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Tracleer, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

#### Pediatric Use

Safety and efficacy in pediatric patients have not been established.

#### Geriatric Use

Clinical studies of Tracleer did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. Clinical experience has not identified differences in responses between elderly and younger patients. In general, caution should be exercised in dose selection for elderly patients given the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in this age group.

#### Hepatic Impairment

Because there is *in vitro* and *in vivo* evidence that the main route of excretion of bosentan is biliary, liver impairment could be expected to increase exposure (C<sub>max</sub> and AUC) of bosentan. Mild liver impairment was shown not to impact the pharmacokinetics of bosentan. The influence of moderate or severe liver impairment on the pharmacokinetics of Tracleer has not been evaluated. There are no specific data to guide dosing in hepatically impaired patients; caution should be exercised in patients with mildly impaired liver function. Tracleer should generally be avoided in patients with moderate or severe liver impairment [see **Dosage and Administration, Warnings and Precautions**].

#### Renal Impairment

The effect of renal impairment on the pharmacokinetics of bosentan is small and does not require dosing adjustment.

**Patients with Low Body Weight** [see **Dosage and Administration**].

#### NONCLINICAL TOXICOLOGY

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

###### Carcinogenesis and Mutagenesis

Two years of dietary administration of bosentan to mice produced an increased incidence of hepatocellular adenomas and carcinomas in males at doses as low as 450 mg/kg/day (about 8 times the maximum recommended human dose [MRHD] of 125 mg twice daily, on a mg/m<sup>2</sup> basis). In the same study, doses greater than 2000 mg/kg/day (about 32 times the MRHD) were associated with an increased incidence of colon adenomas in both males and females. In rats, dietary administration of bosentan for two years was associated with an increased incidence of brain astrocytomas in males at doses as low as 500 mg/kg/day (about 16 times the MRHD). In a comprehensive battery of *in vitro* tests (the microbial mutagenesis assay, the unscheduled DNA synthesis assay, the V-79 mammalian cell mutagenesis assay, and human lymphocyte assay) and an *in vivo* mouse micronucleus assay, there was no evidence for any mutagenic or clastogenic activity of bosentan.

###### Reproductive and Developmental Toxicology

Bosentan was teratogenic in rats given oral doses >60 mg/kg/day. In an embryo-fetal toxicity study in rats, bosentan showed dose-dependent teratogenic effects, including malformations of the head, mouth, face and large blood vessels. Bosentan increased stillbirths and pup mortality at oral doses of

60 and 300 mg/kg/day. Although birth defects were not observed in rabbits given oral doses of up to 1500 mg/kg/day, plasma concentrations of bosentan in rabbits were lower than those reached in the rat. The similarity of malformations induced by bosentan and those observed in endothelin-1 knockout mice and in animals treated with other endothelin receptor antagonists indicates that teratogenicity is a class effect of these drugs.

###### Impairment of Fertility/Testicular Function

The development of testicular tubular atrophy and impaired fertility has been linked with the chronic administration of certain endothelin receptor antagonists in rodents.

Treatment with bosentan at oral doses of up to 1500 mg/kg/day (50 times the MRHD on a mg/m<sup>2</sup> basis) or intravenous doses up to 40 mg/kg/day had no effects on sperm count, sperm motility, mating performance or fertility in male and female rats. An increased incidence of testicular tubular atrophy was observed in rats given bosentan orally at doses as low as 125 mg/kg/day (about 4 times the MRHD and the lowest doses tested) for two years but not at doses as high as 1500 mg/kg/day (about 50 times the MRHD) for 6 months. Effects on sperm count and motility were evaluated only in the much shorter duration fertility studies in which males had been exposed to the drug for 4-6 weeks. An increased incidence of tubular atrophy was not observed in mice treated for 2 years at doses up to 4500 mg/kg/day (about 75 times the MRHD) or in dogs treated up to 12 months at doses up to 500 mg/kg/day (about 50 times the MRHD).

#### PATIENT COUNSELING INFORMATION

Advise patients to consult the Medication Guide on the safe use of Tracleer.

##### Important Information

• Monthly monitoring of serum aminotransferases

The physician should discuss with the patient the importance of monthly monitoring of serum aminotransferases.

• Pregnancy testing and avoidance of pregnancy

Patients should be advised that Tracleer is likely to cause birth defects based on animal studies. Tracleer treatment should only be initiated in females of childbearing potential following a negative pregnancy test. Females of childbearing potential must have monthly pregnancy tests and need to use two different forms of contraception while taking Tracleer and for one month after discontinuing Tracleer. Females who have a tubal ligation or a Copper T 380A IUD or LNG 20 IUS can use these contraceptive methods alone. Patients should be instructed to immediately contact their physician if they suspect they may be pregnant and should seek contraceptive advice from a gynecologist or similar expert as needed.

• Drug Interactions

The physician should discuss with the patient possible drug interactions with Tracleer, and which medications should not be taken with Tracleer. The physician should discuss the importance of disclosing all concomitant or new medications.

**Distributed by:** Actelion Pharmaceuticals US, Inc. South San Francisco, CA 94080, USA

Revised August 2009

**References for previous pages:** 1. Tracleer (bosentan) full prescribing information. Actelion Pharmaceuticals US, Inc. August 2009. 2. Galie N, Rubin LJ, Hooper MM, et al. Treatment of patients with mildly symptomatic pulmonary arterial hypertension with bosentan (EARLY study): a double-blind, randomised controlled trial. *Lancet*. 2008;371:2093-2100. 3. Channick RN, Simonneau G, Sitbon O, et al. Effects of the dual endothelin-receptor antagonist bosentan in patients with pulmonary hypertension: a randomised placebo-controlled study. *Lancet*. 2001;358:1119-1123. 4. Data on file, Actelion Pharmaceuticals.