

Multispecialty Groups Feel Recession's Pinch

BY ERIK GOLDMAN

DENVER — Multispecialty group practice revenue dropped last year for the first time in a decade as practices across the country felt the impact of the recession, but primary care revenue appears relatively healthy.

The Medical Group Management Association's Cost Survey for 2009 showed a 1.9% decline in mean total medical

gross revenue among multispecialty groups, as well as a 9.9% drop in volume of medical procedures (indicated by RVUs provided per patient) and an 11% decrease in total patient volume. Bad debt from fee-for-service charges increased by 13%.

The 2009 report, released at the MGMA's annual conference, was based on 2008 data and so represents a snapshot of the early phase of the recession.

Current conditions could be significantly worse, but won't likely show up until the next survey, said Dr. William F. Jessee, president and chief executive officer of MGMA, who presented the data.

Though fully one-third of practices surveyed reported a decrease in total revenue in 2008, the news isn't all bad. Data on single-specialty groups showed some clear winners, even in these hard

times. In particular, cardiologists reported a 7.9% mean increase in total revenue after operating costs. Pediatricians topped that, with a 9% increase. Family physicians reported a 2.4% mean increase.

Hardest hit were gastroenterologists, with a 5% drop in revenue. In general, the procedure-based specialties are feeling the hardest squeeze, Dr. Jessee noted.

Still, even in the sectors that have seen increases, the percentage increase in gross revenue is only a few points higher than the rising costs of staying in practice, if that much. Many practices, especially the smaller ones, are struggling.

Dr. Jessee said that group practices are tightening their belts.

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ing support staff costs by 1.5%, though there were no reported significant changes in number of staff members. That means only one thing: Many employees have taken pay cuts. In some cases, the doctors themselves are taking home less pay, he pointed out.

Thirty-five percent of practices have instituted hiring freezes, and 34% say they've cut operating budgets. Thirty-seven percent said that they have postponed capital expenditures.

More than one-third of the practices in the survey said that they have seen an increase in the number of uninsured patients in 2008.

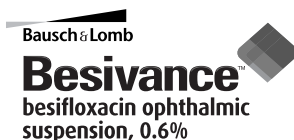
Solo and physician-owned small group practices have been especially hard hit by the recession, and increasingly they are reaching out to hospitals and the large group practices for a lifeline. MGMA surveys over the last decade show clearly that America's doctors are huddling up and selling out to larger health care entities, Dr. Jessee said.

The number of MGMA member groups owned by hospitals grew by 20% during the 5-year period from 2003 to 2008, and they now comprise 10% of the organization's total membership.

During that time, the average number of physicians in MGMA member group practices increased from 16 in 2003 to 19 in 2008.

The number of doctors in the average hospital-owned group rose from 64 to 76, a 19% increase. "There's a big, big trend toward consolidation," Dr. Jessee said.

Not surprisingly, the economic downturn has affected MGMA itself. The organization acknowledged that attendance at this year's annual meeting—roughly 2,150 paid attendees—was down 21% from its peak several years ago.



Brief Summary: Based on full prescribing information revised April 2009.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-323-0000 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS AND USAGE

Besivance™ (besifloxacin ophthalmic suspension) 0.6%, is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria:

CDC coryneform group G
*Corynebacterium pseudodiphtheriticum**
*Corynebacterium striatum**
Haemophilus influenzae
*Moraxella lacunata**
Staphylococcus aureus
Staphylococcus epidermidis
*Staphylococcus hominis**
*Staphylococcus lugdunensis**
Streptococcus mitis group
Streptococcus oralis
Streptococcus pneumoniae
*Streptococcus salivarius**

*Efficacy for this organism was studied in fewer than 10 infections.

DOSAGE AND ADMINISTRATION

Invert closed bottle and shake once before use. Instill one drop in the affected eye(s) 3 times a day, four to twelve hours apart for 7 days.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Topical Ophthalmic Use Only

NOT FOR INJECTION INTO THE EYE.

Besivance™ is for topical ophthalmic use only, and should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

Growth of Resistant Organisms with Prolonged Use

As with other anti-infectives, prolonged use of Besivance™ (besifloxacin ophthalmic suspension) 0.6% may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining.

Avoidance of Contact Lenses

Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance™.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in one clinical trial of a drug cannot be directly compared with the rates in the clinical trials of the same or another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Besivance™ in approximately 1,000 patients between 1 and 98 years old with clinical signs and symptoms of bacterial conjunctivitis.

The most frequently reported ocular adverse event was conjunctival redness, reported in approximately 2% of patients.

Other adverse events reported in patients receiving Besivance™ occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. Oral doses of besifloxacin up to 1000 mg/kg/day were not associated with visceral or skeletal malformations in rat pups in a study of embryo-fetal development, although this dose was associated with maternal toxicity (reduced body weight gain and food consumption) and maternal mortality. Increased post-implantation loss, decreased fetal body weights, and decreased fetal ossification were also observed. At this dose, the mean C_{max} in the rat dams was approximately 20 mcg/mL, >45,000 times the mean plasma concentrations measured in humans. The No Observed Adverse Effect Level (NOAEL) for this embryo-fetal development study was 100 mg/kg/day (C_{max} , 5 mcg/mL, >11,000 times the mean plasma concentrations measured in humans).

In a prenatal and postnatal development study in rats, the NOAELs for both fetal and maternal toxicity were also 100 mg/kg/day. At 1000 mg/kg/day, the pups weighed significantly less than controls and had a reduced neonatal survival rate. Attainment of developmental landmarks and sexual maturation were delayed, although surviving pups from this dose group that were reared to maturity did not demonstrate deficits in behavior, including activity, learning and memory, and their reproductive capacity appeared normal. Since there are no adequate and well-controlled studies in pregnant women, Besivance™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Besifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when Besivance™ is administered to a nursing mother.

Pediatric Use

The safety and effectiveness of Besivance™ in infants below one year of age have not been established. The efficacy of Besivance™ in treating bacterial conjunctivitis in pediatric patients one year or older has been demonstrated in controlled clinical trials [see 14 CLINICAL STUDIES].

There is no evidence that the ophthalmic administration of quinolones has any effect on weight bearing joints, even though systemic administration of some quinolones has been shown to cause arthropathy in immature animals.

Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment Of Fertility

Long-term studies in animals to determine the carcinogenic potential of besifloxacin have not been performed.

No *in vitro* mutagenic activity of besifloxacin was observed in an Ames test (up to 3.33 mcg/plate) on bacterial tester strains *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2uvrA. However, it was mutagenic in *S. typhimurium* strain TA102 and *E. coli* strain WP2(pKM101). Positive responses in these strains have been observed with other quinolones and are likely related to topoisomerase inhibition.

Besifloxacin induced chromosomal aberrations in CHO cells *in vitro* and it was positive in an *in vivo* mouse micronucleus assay at oral doses \geq 1500 mg/kg. Besifloxacin did not induce unscheduled DNA synthesis in hepatocytes cultured from rats given the test compound up to 2,000 mg/kg by the oral route. In a fertility and early embryonic development study in rats, besifloxacin did not impair the fertility of male or female rats at oral doses of up to 500 mg/kg/day. This is over 10,000 times higher than the recommended total daily human ophthalmic dose.

PATIENT COUNSELING INFORMATION

Patients should be advised to avoid contaminating the applicator tip with material from the eye, fingers or other source.

Although Besivance™ is not intended to be administered systemically, quinolones administered systemically have been associated with hypersensitivity reactions, even following a single dose. Patients should be advised to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction.

Patients should be told that although it is common to feel better early in the course of the therapy, the medication should be taken exactly as directed.

Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Besivance™ or other antibacterial drugs in the future.

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besivance™.

Patients should be advised to thoroughly wash hands prior to using Besivance™.

Patients should be instructed to invert closed bottle (upside down) and shake once before each use. Remove cap with bottle still in the inverted position. Tilt head back, and with bottle inverted, gently squeeze bottle to instill one drop into the affected eye(s).

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U.S. Patent No. 6,685,958
U.S. Patent No. 6,699,492
U.S. Patent No. 5,447,926

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