

# Pediatric Quality Measures for Medicaid Released

BY MARY ELLEN SCHNEIDER

Officials at the Centers for Medicare and Medicaid Services recently released an initial set of pediatric quality measures that states can choose to use as part of their Medicaid and State Children's Health Insurance Programs.

The set of 24 measures focuses on prevention and health promotion, immu-

nizations, screening, well-child visits, management of acute and chronic conditions, family experiences with care, and access to services.

The measures are likely to seem familiar to pediatricians since 14 of the 24 are current NCQA Healthcare Effectiveness Data and Information Set (HEDIS) measures reported by Medicaid managed care plans.

The measures are part of an effort by

the federal government to encourage quality reporting within Medicaid and the State Children's Health Insurance Program (SCHIP), but they will be voluntary and the requirements of the program would be up to individual states to determine.

The new measures program was established as part of the Children's Health Insurance Program Reauthorization Act of 2009, which required the federal gov-

ernment to identify a core set of child health quality measures for voluntary use by state programs. The government's charge was to identify existing pediatric measures that are in use by public and private health plans. The initial measure set was developed in consultation with child health care providers, according to CMS.

CMS is seeking public comments on which measures should remain part of the core set, which measures need further development, and what type of technical assistance physicians and other health care providers would need to report on these measures. Comments are due by March 1. Under statute, CMS must make the final measure set available to states by Jan. 1, 2013.

Currently, there is no funding set aside by the federal government to provide financial incentives for successfully reporting on these measures, but CMS and the states are exploring ways that they could encourage voluntary reporting, such as provider incentive payments provided under the American Recovery and Reinvestment Act, according to CMS.

The move to develop pediatric-specific quality measures was praised by the American Academy of Pediatrics. The organization was involved in the creation of the initial measure set and encouraged Congress to invest in the development of measures appropriate for children.

That's definitely an area where pediatricians has fallen behind, said Dr. Stuart A. Cohen, a pediatrician in San Diego and an AAP delegate to the American Medical Association. Right now, pediatric quality measures are mostly built off measures from adult medicine, he said.

There is also a lack of research into what measures would have the greatest impact on quality. Dr. Cohen said that current measurement in pediatrics focuses on areas like immunizations and antibiotic usage, but it's unclear on whether those are the best measures of high-quality pediatric care. He speculated that future research could begin with outcomes of care and work backward to determine what kind of care was given. "We don't have those measures," he said.

Although details about how the measurement program would be set up by the states are still a ways off, Dr. Cohen said he would like to see an appeals process put in place to ensure that physicians have the opportunity to dispute inaccurate data, a safeguard that is in place in most private pay-for-performance programs.

Under the CHIP Reauthorization Act that created the quality measures program, CMS was also tasked with developing an electronic health record format specifically for children. CMS officials are working to coordinate that effort, as well as work on the meaningful-use criteria for EHRs, with the quality-measurement program. ■

A list of each measure and summaries of why they are being recommended are available at [www.ahrq.gov/chip/corebackgrnd.htm](http://www.ahrq.gov/chip/corebackgrnd.htm).



**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](http://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).

Manufactured by: Bausch & Lomb Incorporated  
Tampa, Florida 33637

©Bausch & Lomb Incorporated

U.S. Patent No. 6,685,958

U.S. Patent No. 6,699,492

U.S. Patent No. 5,447,926

Besivance™ is a trademark of Bausch & Lomb Incorporated

\*DuraSite is a trademark of InSite Vision Incorporated

April 2009

9159600