

# Medical Home Standards Focus on Patients

BY MARY ELLEN SCHNEIDER

The National Committee for Quality Assurance has released new standards for practices seeking recognition as a medical home.

The standards now require practices to demonstrate continuity of care by allowing patients to select a personal physician, offering after-hour access to appointments and medical advice, and

having interpreters available and making sure forms and other documents are in the patient's preferred language. The standards also were redesigned to better echo the requirements of the new Medicare and Medicaid programs offering incentives for the implementation of electronic health records.

Most practices are still physician-centric, said Dr. Xavier Sevilla, a pediatrician in Lakewood Ranch, Fla., and a member

of the NCQA Patient-Centered Medical Home Advisory Committee. For example, practices typically open their doors when it's convenient for physicians and offer standard 15-minute appointments for the same reason.

With some of the new standards, NCQA officials are looking to get physicians thinking about things from the patient's point of view, he said.

"There is a big gap between where we

want to go, which is that advanced primary care patient-centered medical home, and what we have right now," Dr. Sevilla said in an interview.

This is the first time the standards have been revamped since they were issued in January 2008. As with the earlier version of the recognition program, the NCQA offers practices three levels of recognition based on points earned for each element of the standards. However, all recognition levels require practices to comply with six "must-pass" elements: access during office hours, using data for population management, care management, supporting the self-care process, tracking referrals and follow-up, and implementing continuous quality improvement.

Starting in 2012, participating practices will receive extra credit if they report the results of a new, standardized patient experience survey. The survey is being developed in collaboration with the Agency for Healthcare Research and Quality and will be a medical home version of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician & Group Survey. It is expected to be released later this year.

Practices will get credit for reporting in 2012, but the NCQA expects to evaluate practices on results in the future.

The updated standards also include more requirements for the use of health information technology and are closely modeled on the federal EHR incentive program that began earlier this year.

For example, the NCQA standards require practices to use an electronic prescribing system that generates and transmits at least 40% of eligible prescriptions to pharmacies. The NCQA also calls on practices to use an electronic system to record up-to-date problem lists, allergies and adverse reactions, smoking status, and a list of prescription medications.

The revised standards are a "paragon of 21st century primary care," NCQA President Margaret E. O'Kane said in a statement. "By emphasizing access, health information technology, and partnerships between clinicians and patients to improve health, these new standards raise the bar in defining high-quality care."

Officials at the NCQA rewrote the standards to be clearer and more specific, but also to be more challenging. Dr. Sevilla, who also serves as chair of the American Academy of Pediatrics Steering Committee of Quality Improvement and Management, advises practices to try to qualify for NCQA recognition in terms of where they are today as a medical home, then use the standards as a "road map" for continuing to improve. But earning 100 points from the start will be very difficult, he said.

The NCQA's medical home recognition program is the organization's fastest growing program. Since December 2008, the number of clinicians recognized through the program has climbed from 214 to 7,676 at the end of 2010. Over the same period, the number of practices recognized as medical homes has risen from 28 to 1,506. ■

important adverse renal effects were observed in clinical studies. Assessments included creatinine clearance; measurements of blood urea nitrogen (BUN), creatinine, and electrolytes in serum; urine specific gravity and pH; and examination of urine sediment. *Studies in Men and Women with Glucocorticoid-Induced Osteoporosis* The safety of FORTEO in the treatment of men and women with glucocorticoid-induced osteoporosis was assessed in a randomized, double-blind, active-controlled trial of 428 patients (19% men, 81% women) aged 22 to 89 years (mean 57 years) treated with  $\geq 5$  mg per day prednisone or equivalent for a minimum of 3 months. The duration of the trial was 18 months with 214 patients exposed to FORTEO and 214 patients exposed to oral daily bisphosphonate (active control). All patients received 1000 mg of calcium plus 800 IU of vitamin D supplementation per day. The incidence of all cause mortality was 4% in the FORTEO group and 6% in the active control group. The incidence of serious adverse events was 21% in FORTEO patients and 18% in active control patients, and included pneumonia (3% FORTEO, 1% active control). Early discontinuation because of adverse events occurred in 15% of FORTEO patients and 12% of active control patients, and included dizziness (2% FORTEO, 0% active control). Adverse events reported at a higher incidence in the FORTEO group and with at least a 2% difference in FORTEO-treated patients compared with active control-treated patients were: nausea (14%, 7%), gastritis (7%, 3%), pneumonia (6%, 3%), dyspnea (6%, 3%), insomnia (5%, 1%), anxiety (4%, 1%), and herpes zoster (3%, 1%), respectively. **Postmarketing Experience:** The following adverse reactions have been identified during postapproval use of FORTEO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. **Osteosarcoma:** Cases of bone tumor and osteosarcoma have been reported rarely in the postmarketing period. The causality to FORTEO use is unclear. Long term osteosarcoma surveillance studies are ongoing. **Hypercalcemia:** Hypercalcemia greater than 13.0 mg/dL has been reported with FORTEO use. Adverse events reported since market introduction that were temporally (but not necessarily causally) related to FORTEO therapy include the following: **Allergic Reactions:** Anaphylactic reactions, drug hypersensitivity, angioedema, urticaria; **Investigations:** Hyperuricemia; **Respiratory System:** Acute dyspnea, chest pain; **Musculoskeletal:** Muscle spasms of the leg or back; **Other:** Injection site reactions including injection site pain, swelling and bruising; oro-facial edema.

## USE IN SPECIFIC POPULATIONS

**Pregnancy Category C.** There are no adequate and well-controlled studies of FORTEO in pregnant women. In animal studies, teriparatide increased skeletal deviations and variations in mouse offspring at doses more than 60 times the equivalent human dose and produced mild growth retardation and reduced motor activity in rat offspring at doses more than 120 times the equivalent human dose. FORTEO should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In animal studies, pregnant mice received teriparatide during organogenesis at subcutaneous doses 8 to 267 times the human dose. At doses  $\geq 60$  times the human dose, the fetuses showed an increased incidence of skeletal deviations or variations (interrupted rib, extra vertebra or rib). When pregnant rats received subcutaneous teriparatide during organogenesis at doses 16 to 540 times the human dose, the fetuses showed no abnormal findings. In a perinatal/postnatal study, pregnant rats received subcutaneous teriparatide from organogenesis through lactation. Mild growth retardation in female offspring at doses  $\geq 120$  times the human dose (based on surface area, mcg/m<sup>2</sup>). Mild growth retardation in male offspring and reduced motor activity in both male and female offspring occurred at maternal doses 540 times the human dose. There were no developmental or reproductive effects in mice or rats at doses 8 or 16 times the human dose, respectively. Exposure multiples were normalized based on body surface area (mcg/m<sup>2</sup>). Actual animal doses: mice (30 to 1000 mcg/kg/day); rats (30 to 1000 mcg/kg/day). **Nursing Mothers:** It is not known whether teriparatide is excreted

in human milk. Because of the potential for tumorigenicity shown for teriparatide in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** The safety and efficacy of FORTEO have not been established in any pediatric population. FORTEO should not be prescribed in patients at an increased baseline risk of osteosarcoma which include pediatric and young adult patients with open epiphyses. Therefore, FORTEO is not indicated for use in pediatric or young adult patients with open epiphyses. **Geriatric Use:** Of the patients receiving FORTEO in the osteoporosis trial of 1637 postmenopausal women, 75% were 65 years of age and over and 23% were 75 years of age and over. Of the patients receiving FORTEO in the osteoporosis trial of 437 men, 39% were 65 years of age and over and 13% were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. **Hepatic Impairment:** No studies have been performed in patients with hepatic impairment. **Renal Impairment:** In 5 patients with severe renal impairment (CrCl < 30 mL/min), the AUC and T<sub>1/2</sub> of teriparatide were increased by 73% and 77%, respectively. Maximum serum concentration of teriparatide was not increased.

## OVERDOSAGE

Incidents of overdose in humans have not been reported in clinical trials. Teriparatide has been administered in single doses of up to 100 mcg and in repeated doses of up to 60 mcg/day for 6 weeks. The effects of overdose that might be expected include a delayed hypercalcemic effect and risk of orthostatic hypotension. Nausea, vomiting, dizziness, and headache might also occur. In postmarketing spontaneous reports, there have been cases of medication errors in which the entire contents (up to 800 mcg) of the FORTEO delivery device (pen) have been administered as a single dose. Transient events reported have included nausea, weakness/lethargy and hypotension. In some cases, no adverse events occurred as a result of the overdose. No fatalities associated with overdose have been reported. **Overdose Management** There is no specific antidote for teriparatide. Treatment of suspected overdose should include discontinuation of FORTEO, monitoring of serum calcium and phosphorus, and implementation of appropriate supportive measures, such as hydration.

## DOSAGE FORMS AND STRENGTHS

Multi-dose prefilled delivery device (pen) for subcutaneous injection containing 28 daily doses of 20 mcg.

## PATIENT COUNSELING INFORMATION

Patients should read the FDA-approved *Medication Guide* and delivery device (pen) *User Manual* before starting therapy with FORTEO and re-read them each time the prescription is renewed. Patients need to understand and follow the instructions in the FORTEO delivery device *User Manual*. Failure to do so may result in inaccurate dosing.

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## PLEASE SEE FULL PRESCRIBING INFORMATION FOR ADDITIONAL INFORMATION.

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