AMA, 99 Other Groups Call for ICD-10 Transition Contingencies

On March 4, the American Medical Association (AMA) and 99 state and professional societies sent a letter urging the Centers for Medicare & Medicaid Services (CMS) to address specific concerns about the potential impact of the transition to the International Classification of Disease 10 (ICD-10) code set in October 2015. The groups are concerned that adequate contingency plans are not in place, with the potential for system failures that could result in a “significant, multibillion dollar disruption for physicians and serious access to care issues for Medicare patients.”

Recently released end-to-end testing results indicated that Medicare claims acceptance rates would fall from 97% to 81% if ICD-10 were implemented today. That decline in acceptance could cause a backlog of millions of unpaid Medicare claims. In a press release, the AMA noted on behalf of the 100 groups signing the letter that this end-to-end testing represented <1% of all Medicare claims and included providers who are significantly better prepared for ICD-10 than many of their peers, so that the actual acceptance rate could be much worse. “The likelihood that Medicare will reject nearly 1 in 5 of the millions of claims that go through our complex health care system each day represents an intolerable and unnecessary disruption to physician practices,” said AMA President Robert M. Wah, MD. “Robust contingency plans must be ready on day 1 of the ICD-10 switchover to save precious health care dollars and reduce unnecessary administrative tasks that take valuable time and resources away from patient care.”

The groups writing the letter to CMS called for consideration of the ways in which the transition to ICD-10 will affect quality reporting programs, such as the Physician Quality Reporting System (PQRS) and Meaningful Use (MU) efforts. Because PQRS and MU quality reporting periods are based on the calendar year and the switch to ICD-10 will occur well into 2015, quality measures will be reported and tabulated with both ICD-9 and ICD-10 codes. This will be especially challenging for measures that capture encounters pre- and postvisit for services that occur before and after the transition deadline, so that physicians will be required to report ICD-9 for the first segment of care and ICD-10 for the final.

“Although we appreciate the training, educational tools and other efforts by CMS to prepare physicians for the ICD-10 transition, it is clear that more information is needed about how the shift will impact quality reporting so physicians can avoid penalties,” said Wah.

American Medical Association


Lenvatinib Receives Approval in DTC

The U.S. Food and Drug Administration (FDA) on February 13 announced approval of the kinase inhibitor Lenvima (lenvatinib; Eisai Inc., Woodcliff Lake, NJ) to treat patients with progressive, differentiated thyroid cancer (DTC) with radioactive iodine–refractory disease. “The development of new therapies to assist patients with refractory disease is of high importance to the FDA,” said Richard Pazdur, MD, director of the Office of Hematology and Oncology Products in the FDA Center for Drug Evaluation and Research. “Today’s approval gives patients and health care professionals a new therapy to help slow the progression of DTC.”

Lenvima was reviewed under the FDA’s priority review program, which facilitates expedited review of drugs with the potential to provide significant improvement in safety or effectiveness in treatment of serious conditions. The drug also received orphan product designation, because it is intended to treat a relatively rare disease status. Lenvima was approved 2 months ahead of the prescription drug user fee goal date of April 14, the date on which the FDA was originally scheduled to complete its review of the application.

The announcement of approval came 1 day after publication of a study on “Lenvatinib versus placebo in radiodine–refractory thyroid cancer” in the New England Journal of Medicine (2014;372:621–630) by Martin Schlumberger, MD, and members of the Tumeurs de la Thyroïde Refractaires Network for the Essai Stimulation Ablation Equivalence Trial. This phase 3 multicenter trial included 392 patients with 131I-refractory DTC who were randomly assigned to lenvatinib treatment (n = 261; 24 mg/d in 28-d cycles) or placebo (n = 131). Patients in the placebo group were eligible to initiate lenvatinib treatment at time of progression. Median progression-free survival rates were 18.3 and 3.6 mo for the treatment and placebo groups, respectively. In the treatment group, the overall response rate was 64.8% (4 complete and 165 partial responses), whereas this percentage was only 1.5% in the placebo group.

The study noted both common and serious side effects of lenvatinib administration, and these were detailed in the FDA approval announcement. In the study, the drug was discontinued because of the severity of these adverse effects in 14.2% of patients (n = 37), and 6 of 20 deaths that occurred during the study period were considered by the authors to be lenvatinib-related. In the lenvatinib group, >40% of patients experienced side effects, including hypertension (67.8%), diarrhea (59.4%), fatigue or asthenia (59.0%), decreased appetite (50.2%), decreased weight (46.4%), and nausea (41.0%). Serious but rare potential side effects are also listed in the FDA approval.

U.S. Food and Drug Administration
The New England Journal of Medicine
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