FDA Finds Injectable Anemia Drug ‘Not Approvable’

By Damian McNamara

Fort Lauderdale, Fla. — Pay-for-performance evaluations of physicians will require additional reimbursement measures, some justify the provision of some services.

Medicare and private insurers historically have used coding for financial reimbursement, but the government and insurers began “profiling” all physicians based on claims data about 3 years ago, Dr. Barbara Levy said at a meeting on hysterectomy sponsored by the Cleveland Clinic.

“We are designing additional ICD-9 codes because of pay for performance,” said Dr. Levy, a member of the Code and Nomenclature Committee of the American College of Obstetricians and Gynecologists.

For example, one of the quality measures from HEDIS (the Healthcare Effectiveness Data and Information Set) promotes regular pap smears for cervical cancer screening, except for patients who had a hysterectomy for benign disease. “We did not have an ICD-9 code for this until this year: ‘Patient no longer has organ.’ So now the payers will know that we did not do a pap smear for a good reason. And they are extrapolating this information to judge our quality,” said Dr. Levy, also the medical director of the Women’s Health and Breast Center, Franciscan Health System, Federal Way, Wash.

Oh gyns. should begin collecting their own case data, including outcomes, instead of waiting for the government or others to do it. “We need to learn to be stewards of our resources and pay attention to what things cost.” She calculated a $4,800 overall cost per case for laparoscopic supraventricular hysterectomy at her institution, for example.

A physician who uses more resources per patient during a particular period of time will be paid less, per the program’s efficiency measures.

Use Additional Codes to Cope With Pay for Performance

By Damion McNamara

Miami Beach

Higher disease activity, treatment with cyclophosphamide, older age, and a certain ethnic background were each linked with a significantly increased risk for developing premature gonadal failure in a study of 316 women with systemic lupus erythematosus.

Disease activity and Texan-Hispanic ethnicity had not previously been reported to boost the risk for premature gonadal failure (PGF) in younger women with systemic lupus erythematosus (SLE), report the authors.

Altogether, PGF treatment is not recommended for treating young women with SLE, said Dr. González and his associates.

They used data collected in the Lupus in Minorities: Nature vs. Nurture (LUMINA) study, a longitudinal outcomes study that included SLE patients aged 16 or older who were diagnosed with SLE for 5 years or less. From this group, they focused on women younger than 40 years of age who were not postmenopausal when they enrolled.

This yielded a study group of 316 women, with an average age of about 29 years. Their average duration of SLE at enrollment was 1 year. The group included women from four racial and ethnic groups: Texas-Hispanics, Puerto Rican-Hispanics, African Americans, and whites.

During follow-up, 37 women (12%) developed PGF. The total group of 316 women included 76 who were treated with cyclophosphamide, of whom 33% developed PGF. Women categorized as having unclassified SLE at diagnosis were almost fivefold more likely to develop PGF compared with white women.

A number of committee members advised that if the FDA chose to approve the product, the label should be limited to women for whom oral iron is not effective. Most of those voting in favor of approval said off-label use should be limited, especially in chronic kidney disease patients.

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