CMS Unlikely to Cover Genetic Warfarin Test

BY ALICIA AULT

There is not enough evidence to support coverage of pharmacogenomic testing that predicts a patient's response to warfarin, the Centers for Medicare and Medicaid Services said.

The testing can be covered if it is part of a prospective, randomized trial that meets certain criteria proposed by the agency, the CMS said. The study should determine whether the test can predict the frequency and severity of hemorrhage, thromboembolism related to the primary indication for anticoagulation, other thromboembolic events, and mortality, the agency noted. And any trial should determine whether the results are generalizable to the Medicare population.

There are a number of lab tests already approved by the FDA, and many labs offer so-called "home-brew" tests. Although there is evidence that these tests accurately identify people with certain gene variants that may heighten their responsiveness to warfarin, there is no direct evidence of any improvement in health as a result, the agency said.

In February, a Medicare Evidence Development and Coverage Advisory Committee determined that there were not enough data to support national coverage of the testing.

The CMS said trials may show genetic testing to be of benefit. "The ability to more effectively treat or prevent blood thrombosis and avoid the risk of hemorrhage due to overanticoagulation by guiding warfarin dosing based on genetic testing results would be a worthwhile potential benefit for the numerous Medicare beneficiaries, perhaps exceeding 1 million annually, who are initiating anticoagulant therapy," the agency noted. ■