ADVISORY PANEL ON CLINICAL DIAGNOSTIC LABORATORY TESTS
Recommendations
September 12, 2016

Automated Test Panels

1. The Panel recommends that CMS pay for CPT panels and for single-test CPT codes using data gathered under the Protecting Access to Medicare Act of 2014 (PAMA).

2. The Panel recommends that CMS use PAMA data for Current Procedural Terminology (CPT) panels and that CMS create G codes based on the number of analytes performed for any additional analytes billed beyond the CPT panel.

Advanced Diagnostic Laboratory Test (ADLT) Application Process

3. The Panel recommends that CMS' application for ADLT status require applicants to include a local coverage determination or national coverage determination to demonstrate that the test is covered under Medicare Part B.

4. The Panel recommends that CMS' application for ADLT status require applicants to 1) attest that, to the applicant's knowledge, the test is offered and furnished only by a single laboratory other than the original developing laboratory (or a successor owner) and 2) include a tax identification number.

5. The Panel recommends that CMS' application for ADLT status require applicants to:
    a. attest that the applicant has not sold the test to other laboratories;
    b. attest that the applicant has not licensed the test to other laboratories;
    c. attest that the applicant will report to CMS if it sells the test to other laboratories;
    d. attest that the applicant will report to CMS if it licenses the test to other laboratories; and
    e. attest that the applicant will report to CMS if the applicant laboratory is sold/successor.

6. The Panel recommends that CMS' application for ADLT status require applicants to include a unique HCPCS code, an application for a unique CPT code, or a request that CMS create a unique G code.

7. The Panel recommends that CMS' application for ADLT status require, if applicable, that the applicants attest that the test is cleared or approved by the U.S. Food and Drug Administration (FDA) and provide documentation as well as the FDA premarket approval or premarket notification (i.e., 510[k]) number.

8. The Panel recommends that CMS' application for ADLT status require applicants to name the component biomarkers of the algorithm and provide a general description of the analysis performed in the test.

9. The Panel recommends that CMS' application for ADLT status require applicants to attest that they will notify CMS of changes to the biomarkers or algorithms of their tests.

10. The Panel recommends that CMS' application for ADLT status require applicants to attest that the test algorithm is unique.

11. The Panel recommends that CMS' application for ADLT status require applicants to provide a summary, intended use and patient-specific result of the test. A sample report is recommended.

12. The Panel recommends that CMS' application for ADLT status require applicants to 1) attest that the ADLT provides new information not available from other tests; 2) provide information regarding other tests that may overlap with the intended use or attributes of this test; and 3) provide information that is essential (similarities/differences) to determine that the proposed ADLT provides new information not available from other tests.

13. The Panel recommends that, if CMS requires any proprietary or confidential information to be submitted as part of the ADLT application, CMS must protect all non-public information from disclosure via a well-articulated policy and guidelines and provide an avenue of appeal for the applicants.