The Coalition for 21st Century Medicine
Recommendations on the CY2016 Preliminary Payment Determinations
for the Advisory Panel on Clinical Diagnostic Laboratory Tests
October 19, 2015

On August 26, 2015, the Advisory Panel on Clinical Diagnostic Laboratory Tests met for the first time, and made recommendations regarding pricing methodologies for new codes subject to pricing determinations for CY 2016. With respect to nine codes representing eight Multianalyte Assays with Algorithmic Analyses (MAAAs), the Panel recommended that CMS establish payment amounts for these tests using the *gapfill* methodology. On September 25th, the Centers for Medicare and Medicaid Services recommended that payment amounts for these tests be determined using the *cross-walk* methodology. **The Coalition for 21st Century Medicine recommends that the Panel affirm its August 26th recommendation that CMS use gapfilling to establish payment amounts for the nine MAAA codes under review for CY 2016.**

- Crosswalking is not a suitable approach to price these tests.
  - Crosswalking is suitably used to determine payment rates when "a new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code." (42 CFR 414.508(a)).
  - There are no comparable tests currently paid on the CLFS.
  - The American Medical Association acknowledged the unique nature of each MAAA test when it developed new codes specific to each test, and established a distinct section of the CPT code set specifically for creating and grouping codes for MAAAs.

- Gapfilling is the appropriate process for CMS to use to price these new MAAA codes.
  - In prior years, CMS consistently recommended that payment amounts for MAAAs be established through the gapfill methodology. In previous years, when MAAA codes came before CMS for consideration, the agency recognized the unique nature of the MAAAs, concluded that there were no appropriate analogs on the CLFS upon which to base a payment determination, and recommended that payment amounts for those MAAAs be established through the gapfill methodology. Because of this history of relying on Medicare Administrative Contractors to establish payment amounts through gapfilling, MACs have established gapfilling procedures to review clinical and financial data from sponsoring laboratories, and to establish acceptable Medicare payment amounts. These procedures include the collection and consideration of detailed dossiers supporting each test.
  - All of the stakeholders with experience performing these tests recommended gapfilling as the methodology for pricing these tests.

Code	Description	Advisory Panel Recommendation August 26, 2015	CMS Preliminary Determination September 25, 2015	Coalition Recommendation October 19, 2015
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score	Gapfill	Crosswalk	Gapfill
81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score	Gapfill	Crosswalk	Gapfill
81525	Oncology (colon), mRNA, gene expression profiling by realtime RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score	Gapfill	Crosswalk	Gapfill
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination	Gapfill	Crosswalk	Gapfill
81536	+ Each additional single drug or drug combination (List separately in addition to code for primary procedure)	Gapfill	Crosswalk	Gapfill
81538	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival	Gapfill	Crosswalk	Gapfill
81540	Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype	Gapfill	Crosswalk	Gapfill
81545	Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	Gapfill	Crosswalk	Gapfill
81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score	Gapfill	Crosswalk	Gapfill