

How Will the “\$1,000 Dollar Genome” Meet Reality (and Centers for Medicare & Medicaid Services)?

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Much has been written recently about the remarkable transformation new DNA sequencing technologies are bringing to medicine, delivering vast amounts of genetic information speedily and with ever-decreasing cost. Glib references to “the \$1,000 dollar genome” have emphasized the point that “soon” complete genomic analysis will be possible for less than the charge for a computed tomography scan of the chest, abdomen, and pelvis (current procedural terminology code 74178). Recent estimates indicate more than 68 million computed tomography scans are done in the United States each year. Cost estimates for genome analysis virtually never take into account the realities of the development and reimbursement strategies for novel clinical laboratory assays. Genomic-based clinical laboratory tests are increasingly common, and the processes that typically determine appropriate reimbursement for these tests are being challenged by their unique nature.

In 2013, several expert working groups were commissioned by the American Medical Association Current Procedural Terminology (AMA CPT) Editorial Panel to develop CPT codes that describe genomic sequencing procedure (GSP) services, which will be provided by laboratory tests using genomic sequencing technologies. These codes were debated and accepted by the panel earlier this year and, although not perfect, represent an earnest attempt by knowledgeable stakeholders, including payers, to create useful and meaningful codes.

On Monday, July 14, 2014, the Centers for Medicare & Medicaid Services (CMS) held the Annual Clinical Laboratory Fee Schedule Public Meeting in Baltimore, Maryland. During the first half of this meeting, several groups presented public commentary regarding the most “appropriate” pricing methodology (eg, gapfilling versus crosswalk; see Table) for new CPT codes. Discussion surrounded those codes accepted by the AMA CPT Editorial Panel for genomic sequencing-based assays (eg, 814XX, targeted

genomic sequencing; see Figure), which are to be implemented by CMS on January 1, 2015. At this meeting, Roswell Park Cancer Institute) and multiple other groups (eg, Sequenom Laboratories, the American Society for Clinical Pathology, the American Clinical Laboratory Association, the Coalition for 21st Century Medicine, Foundation Medicine, and the American Society for Clinical Laboratory Science) recommended gapfill. Organizations including the Association for Molecular Pathology and the College of American Pathologists recommended crosswalk, in large part, motivated by the less-than-optimal implementation by CMS of the gapfill process for pricing the tier 1 and tier 2 molecular pathology procedure CPT codes in 2013. There remain many tests used clinically with accurate codes, which have not been priced by CMS or its contactors. Hence, various personalized medicine innovations are not available to many people. Although it is unknown whether crosswalking or gapfilling methodology will be adopted by CMS to determine reimbursement for next-generation sequencing-based tests, the outcome of this could be critically important to patient care for many years.

Regardless of which methodology is used, individual groups concerned with cancer care, such as Roswell Park Cancer Institute, sense the urgency for this void to be filled. Remarkably, this debate is occurring in the shadow of the recent US House bill HR 4302 Protecting Access to Medicare Act of 2014 (PAMA; 113th Leg, Pub L No. 113-93), where there is language requiring the Secretary of Health, not later than July 1, 2015, to establish a permanent clinical laboratory advisory panel to assist CMS on coverage and payment matters related to clinical diagnostic laboratory tests. This panel, to be composed of individuals with expertise in clinical- and research-based molecular pathology and with appropriate expertise in laboratory science and health economics, will assist the Secretary of Health and CMS in the establishment of payment rates for new clinical

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Gapfilling Versus Crosswalk

In the *crosswalk* process, a new test is determined to be similar to an existing test or tests, and a reimbursement value can be reasonably assigned to it using whole or fractional amounts for the related codes from existing fee schedules. When no comparable test is available, the *gapfill* process is used. Each Medicare carrier determines a payment amount for its area for use in the first year using a variety of disparate pricing tools. Centers for Medicare & Medicaid Services then uses the carrier-set amounts to establish a national limitation amount at the end of the gapfill year.

Test purpose and method:
Genomic sequencing procedures and other molecular multianalyte assays

New test code and descriptor:
814XX Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (eg, *ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET*), and interrogation for sequence variants and copy number variants or rearrangements, if performed

Recommendation for determining payment for new costs:
Gapfilling versus crosswalking

Current procedural terminology codes for cancer-related genomic sequencing procedures as presented at the 2014 Centers for Medicare & Medicaid Services Annual Clinical Laboratory Fee Schedule Public Meeting.

diagnostic laboratory tests, such as those dependent on genomic sequencing methods, using either a crosswalking or gapfilling process. If a gapfill methodology is chosen to establish reimbursement for GSPs, and if it is to be pursued effectively, laboratories performing such testing must provide detailed information to Medicare carriers, CMS, and this panel about the cost and other associated factors of such testing. It is equally important that CMS establish a transparent procedure to fairly and knowledgeably evaluate these data in determining coverage and reimbursement decisions, particularly if implementation of the gapfill process is relegated to the individual Medicare carriers. There is appropriate concern from stakeholders that reimbursement rates will be set on January 1, 2015, based on questionable crosswalk reasoning or using the flawed gapfill process CMS relied on in 2013 for the tier 1 and tier 2 molecular pathology codes before this PAMA-directed advisory panel can be seated.

Evidence was presented at the July Annual Clinical Laboratory Fee Schedule meeting that fair and equitable reimbursement for genomic sequencing-based tests may require more-specific CPT codes, yet to be developed, to adequately recognize the services provided. The number of genes and/or exons analyzed and interpreted in a given

targeted genomic sequencing assay is directly related to the costs associated with a given test, but the relationship is neither linear nor continuous. Whichever method is used to determine reimbursement for GSPs, gapfilling or crosswalking, a defined methodology is needed to establish rational, evidence-based reimbursement rates for the various genomic sequencing-based tests and services. The necessary data can only be provided by participating clinical laboratories.

In summary, clinical laboratories are poised to move forward with advances made possible by genomic sequencing technologies that will form the foundation for much of patient care in a more-efficient manner than ever before. To do so will require an equally innovative and dedicated effort by CMS and other government officials to establish appropriate reimbursement for genomic sequencing-based tests at a national level that ensures that all Americans have access to this new disruptive technology. Implementation of personalized medicine testing will require consideration that reimbursement for GSPs occurs at a national level. Otherwise, this process may become one that is limited only to those individuals with the resources to pay for this testing themselves.

EDITOR'S NOTE

In early October, the Centers for Medicare and Medicaid Services (CMS) announced its intent to use the gapfill methodology to determine payment for the genomic sequencing procedures described by the 21 new Current Procedural Technology codes that will go into effect on January 1, 2015. On October 27, CMS announced the establishment of an Advisory Panel on Clinical Diagnostic Laboratory Tests¹ and requested nominations for individuals to serve on the panel.

1. US Department of Health and Human Services. Centers for Medicare & Medicaid Services. *Federal Register*. Oct 27, 2014; 79(207):63919–63920.