Ins and Outs of Molecular Pathology Coding

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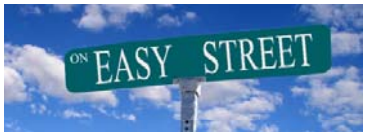
Overview

- Review new molecular procedure code structure
- Highlight new Tier 1 and Tier 2 codes
- CMS final payment decision for CLFS placement
- Walk through specific coding examples
- Summary

Unit of Service



One Code = One Test or Procedure = One Payment

Molecular Pathology Procedures

Tier 1 Individual analyte codes for higher volume tests	**Tier 2** 9 Complexity based codes for less common tests	**MAAA** Multi-analyte assays using algorithm analysis
106 codes	539 analytes	9 category 1 codes 5 administrative

Tier 1 2013 Additions

- ***APC*** *(adenomatous polyposis coli)* (eg, familial adenomatosis polyposis [FAP], attenuated FAP)
- ***EGFR*** (*epidermal growth factor receptor*) (eg, non-small cell lung cancer) gene analysis; common variants)
- ***GJB2*** *(gap junction protein, beta 2, 26kDa; connexin 26)* (eg, nonsyndromic hearing loss)
- ***GJB6*** *(gap junction protein, beta 6, 30kDa; connexin 30)* (eg, nonsyndromic hearing loss)
- ***PTEN*** *(phosphatase and tensin homolog)* (eg, Cowden syndrome)
- ***PMP22*** *(peripheral myelin protein 22)* (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies)
- **81479** Unlisted molecular pathology procedure
- **DMD** *(dystrophin)* (eg, Duchenne/Becker muscular dystrophy) deletion analysis

Tier 2 Code Structure

	Variants	Somatic or Methylation Variants	Dup/Del or Mut Scanning Exons	Multiplex PCR Amplicons /Reactions	DNA Sequence Exons	Also includes:
81400 - Level 1	1					
81401 - Level 2	2-10	1				PCR for triplet repeat/dynamic mut
81402 - Level 3	>10	2-10	1			Gene rearrangements
81403 - Level 4			2-5	>10/≥2	1	
81404 - Level 5			6-10		2-5	Southern for triplet repeat/dynamic mut
81405 - Level 6			11-25		6-10	
81406 - Level 7			26-50		11-25	Cytogenomic array for neoplasia
81407 - Level 8			>50		26-50	Sequence analysis of multiple genes on 1 platform
81408 - Level 9					>50	

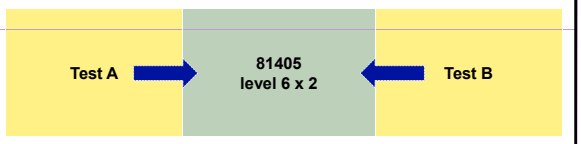
Tier 2 Code Example

- **81403** Molecular pathology procedure, **Level 4** (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiple PCR in 2 or more independent reactions, mutation scanning or duplications/deletion variants of 2-5 exons)

  ABL1 (c-abl oncogene 1, receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), variants in the kinase domain
  ANG (angiogenin, ribonuclease, RNase A family, 5) (eg, amyotrophic lateral sclerosis), full gene sequence
  CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), full gene sequence

Multi-Analyte Tier 2 Code "Stacking" Problem

- Rare constitutional disorder requires testing of multiple genes all in the same level



Multi-analyte Assays With Algorithmic Analyses

MAAA

- Procedures that use multiple results and an algorithmic analysis to derive a single result, typically reported as a numeric score or probability
- Usually unique to a single clinical laboratory or manufacturer

MAAA Code Descriptor

- **Disease type** (eg, oncology, autoimmune, tissue rejection)
- **Material(s) analyzed** (eg, DNA, RNA, protein, antibody)
- **Number of markers** (eg, number of genes, number of proteins)
- **Methodology(ies)** (eg, microarray, RT-PCR, ISH, ELISA)
- Number of **Functional domains** (if indicated)
- **Specimen type** (eg, blood, fresh tissue, formalin-fixed paraffin embedded)
- **Algorithm** result type (eg, prognostic, diagnostic)
- **Report** (eg, probability index, risk score)

MAAA for 2013

Category I code

- 81512 Fetal chromosomal abnormalities, biochemical assays of five analytes (AFG, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score

Administrative code set (Appendix O)

- 0001M HCV FibroSURE™, LabCorp
  Infectious disease, HCV, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver
- 81599 Unlisted multianalyte assay with algorithmic analysis

CMS Final Payment Determination

- CMS Final Payment Decision
  - www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html
- Tier 1 and Tier 2 codes (81200 through 81408)
  - Clinical Laboratory Fee Schedule (CLFS) placement
  - **Gap-filling**
- Multi-analyte Assays with Algorithmic Analyses (MAAAs, 81500-81599 and Appendix O)
  - CMS will not recognize these MAAA codes as valid for Medicare purposes under the CLFS for CY 2013.
    - …since CMS uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done.

HCPCS G-code, G0452

- G0452 Molecular diagnostics; interpretation and report
  - Considered a "clinical laboratory interpretation service,"
    - which is one of the current categories of PFS pathology services under the definition of physician pathology services at §415.130(b)(4)
  - Certain specific requirements for billing the professional component must be met including that the interpretation
    1. must be requested by the patient's attending physician,
       - "…a hospital's standing order policy can be used as a substitute for the individual request by a patient's attending physician."
    2. must result in a written narrative report included in the patient's medical record
    3. requires the exercise of medical judgment by the consultant physician

    Section §415.130(b)(4) of the regulations and section 60 of the Claims Processing Manual (IOM 100-04, Ch. 12, section 60.E.)

G0452 RVU

- The 83912-26 current work RVU of 0.37 is the same as nearly all the clinical laboratory interpretation service codes
- Is within range of AMA RUC- recommended values for the molecular pathology CPT codes
  - The utilization-weighted average AMA RUC recommended work RVU was 0.33, and the median AMA RUC-recommended work RVU was 0.45 for the molecular pathology CPT codes.
- CMS set the RVU at 0.37 and assigned 5 minutes of pre-service time, 10 minutes of intra-service time, and 5 minutes of post-service time on an interim final basis for CY 2013
- CMS requested public comment on the interim final values

Gap-fill Process

- CMS requires individual Medicare contractors (Palmetto, WPS, etc.) to determine reimbursement their coverage regions
- CMS must post interim contractor-specific amounts by April 30
- Comment period for 60 days ensues
- CMS select the median price from all the contractors to set the National Limitation Amount
- CMS will accept reconsideration requests for 30 days after final amounts are posted
- National Limitation Amounts go into effect Jan.1, 2014
- Palmetto and Cahaba have posted their preliminary amounts

Our FLT3 assay tests for both ITD and D835 mutations.

- **Code Options**: 81245 (FLT3 exons 14, 15)
- Code with 81245 for ITD mutation and 81479 (unlisted) for the D835 mutation

How should one code for CF testing?

- **Code Options**: CFTR family of 81220, 81221, 81222, 81223, and 81224
- Carrier screening using the ACMG/ACOG panel of variants: code with 81220
- Diagnostic testing of affected patient with identification of a deltaF508 mutation by common variant panel testing and a unique point mutation by full gene sequencing: code with 81220 and 81223

What is the best code option for Beta thalassemia testing of 59 mutations?

- **Code Options**: 81401 (HBB listed under tier 2 level 2), 81479
- Code with 81401 for the Beta thalassemia mutation common variants including HbS, HbC and HbE (up to five variants) and with 81479 once to cover the other less common variants
- Recommend submitting a coding change proposal to the AMA to amend the current codes or to create a new one

How should BCR-ABL testing be coded for the Asuragen assay?

- **Code Options**: 81206, 81207, and 81208
- Diagnostic RT-PCR testing for the t(9:22) major and minor breakpoints: code with 81206 and 81207
- Periodic monitoring for imatinib response or failure using quantitative RT-qPCR for the appropriate t(9:22) fusion transcript: single code with the appropriate fusion transcript breakpoint, most often major: code with 81206
- Asuragen assay is multiplexed for both major and minor breakpoints: code with 81206 and 81207

What if I test for the KRAS codon 12, 13 and 61 mutations?

- **Code Options**: 81275 (KRAS codon 12, 13), 81403 (KRAS exon 2 listed in Tier 2, level 4) and 81405 (KRAS full gene sequence listed in level 6)
- KRAS codon 12, 13 and 61, mutation testing: code with 81275 and 81403
- KRAS full gene sequencing: code with 81405

How should we code for screening for several mutations associated with JMML?

- We use next gen sequencing for KRAS exons 2 & 3, NRAS exons 2 & 3, PTPN11 exons 3, 4 & 13 and CBL exons 8 & 9
  - **Code Options**: 81275 (KRAS codons 12, 13), 81403 (KRAS exon 3 sequence) and 81404 (NRAS exons 2 & 3 in level 5)
  - Code with 81275, 81403, 81404 and 81479

Can G0452 be used with 87798-infectious agent…amplified probe technique?

- Probably not
- CMS defined G0452 as molecular pathology procedure; physician interpretation and report
- CPT had not permited use of molecular interpretation and report with microbiology testing
- However, if you provide a consultation then one could consider using 80500 for a clinical pathology consultation

I would like to have input on how best to code for a SNP microarray analysis with over 1 million markers.

- If this assay does not match the service as currently defined in the two genome-wide codes 81228 and 81229, for now the option is to code with 81479 unlisted code
- Recommendation is to submit a coding change proposal to the AMA to amend the current codes or to create a new one

Array CGH

- **81228** Cytogenomic **constitutional** (genome-wide) microarray analysis; interrogation of genomic regions **for copy number variants** (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
- **81229** interrogation of genomic regions **for copy number and single nucleotide polymorphism** (SNP) variants for chromosomal abnormalities

  ►(Do not report 81228 in conjunction with 81229)◄
- **81405** Cytogenomic constitutional targeted microarray analysis of **chromosome 22q13** by interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities

  … **of the X chromosome**…

  ►(When performing genome-wide cytogenetic constitutional microarray analysis, see 81228, 81229)◄
- **81406** Cytogenomic microarray analysis, **neoplasia** (eg, interrogation of copy number, and loss-of-heterozygosity via single nucleotide polymorphism [SNP]-based comparative genomic hybridization [CGH] microarray analysis)

How are institutions approaching billing of the interpretation code (G0452)?

- Some laboratories identify in the order that the result will include an interpretative report unless the clinician opts out
- Others have institutional standing policies explaining that an interpretative report is included when testing is requested

Requesting a New Code – The Process

- Submit a completed Coding Change Proposal (CCP) to the AMA
  - http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes/request-form-instructions.page
- AMA CPT Editorial Panel staff collates all CCP submissions
- Molecular code proposals are given to the MPAG to review and provide recommendation first
- Then the CCP and the MPAG review goes to the PCC (Pathology Coding Caucus run by CAP) to recommend to the AMA CPT Editorial Committee
- They ultimately decide to accept or reject the proposal

Summary

- Several new codes and analytes added for 2013
  - Tier 1: 106 codes
  - Tier 2: 182 published additions to the original 99 analytes, with a total of 539 that have been accepted
  - Creation of a unlisted code
  - 14 MAAA's
    - 9 with Category 1 codes
    - 5 with Administrative status only

Summary

- CMS placed the codes on the CLFS fee schedule
- Gap-filling process will be used to determine pricing
- Labs cannot self-assign with a Tier 2 level if the analyte is not identified
  - Tests that do not yet have a code will be required to use the new unlisted code (81479)
  - Recommend submitting CCPs to the AMA

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Other New Codes with Molecular Relationship

- **86152** **Cell enumeration** using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood);
- **87910** Infectious agent genotype analysis by nucleic acid (DNA or RNA); **cytomegalovirus**
- **87912** Infectious agent genotype analysis by nucleic acid (DNA or RNA); **Hepatitis B virus**
- **87631** Infectious agent detection by nucleic acid (DNA or RNA); **respiratory virus** (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, **3-5 targets**
- **87632** Infectious agent detection by nucleic acid (DNA or RNA); **respiratory virus** (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, **6-11 targets**
- **87633** Infectious agent detection by nucleic acid (DNA or RNA); **respiratory virus** (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, **12-25 targets**