Overview of the AMA Molecular Pathology CPT codes

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Reimbursement and CPT codes

- CPT code ≠ reimbursement
- List of services

CPT CODES

Before January 1, 2013

- Used Molecular “stacking” CPT codes to get reimbursed
  - Each step of test utilized a different CPT code to create a “stack”

Creation of New AMA CPT codes for MolPath

- Tier 1
- Tier 2
- Multianalyte Assays with Algorithmic Analyses (MAAAs)

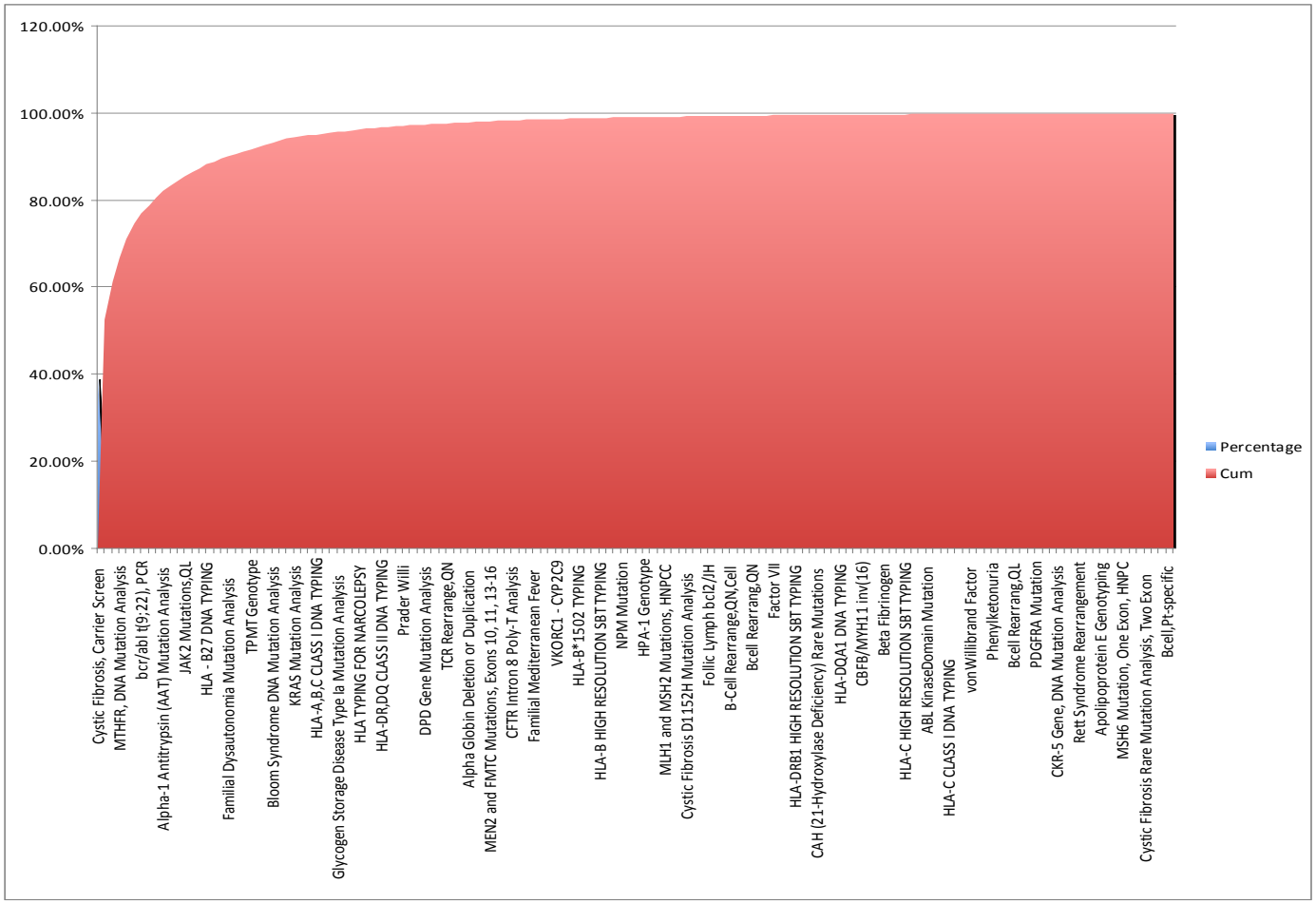
Why the new Molpath CPT codes?

- Payers wanted to know for what they were paying
- Needed clear and granular system

Relative Laboratory Testing Percentages

- Large reference laboratories
- Medium reference laboratories

Relative Percentage of Tests from Labs



New MolPath codes

- Tier 1 = analyte specific code
- Tier 2 = level of complexity code

- Current list available: ***ama***-*assn.org/resources/doc/cpt/mo****path***-*maaa-tier1-tier2.pdf*

CPT Tier 1 Descriptor

- *HUGO approved gene symbol (HUGO approved gene name)* (eg, disease state/condition) gene analysis; analysis type

Descriptor Caveats

- Disease state/condition is not an all inclusive list
- Common gene variant names are used
- The code includes all analytical services performed in the test (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection)
- All analyses are qualitative unless otherwise noted

CPT Codes Tier 1 – *BCR/ABL*

- **81206 -** *BCR/ABL1 (t(9:22))* (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative

  81207 - Minor breakpoint, qualitative or quantitative

  81208 - Other breakpoint, qualitative or quantitative

CPT Codes Tier 1 – *CFTR*

- **81220 -** *CFTR (cystic fibrosis transmembrane conductance regulator)* (eg, cystic fibrosis) gene analysis; common variants (eg, ACOG/ACMG guidelines)

  81221 - Known familial variants

  81222- Duplication/deletion variants

  81223 - Full gene sequence

  81224 - Intron 8 poly T analysis (eg, male infertility)

CPT Codes Tier 1 – aCGH

- **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)

Tier 2

- Less common; lower volume assays
- Divided into 9 levels of complexity
- ~ 600 descriptors

81400 - Tier 2; level 1

- **Identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis**

ACADM *(acyl-CoA dehydrogenase, C-4 to C-12 straight chain, MCAD)* (eg, medium chain acyl dehydrogenase deficiency), K304E variant

ACE *(angiotensin converting enzyme)* (eg, hereditary blood pressure regulation), insertion/deletion variant

AGTR1 *(angiotensin II receptor, type 1)* (eg, essential hypertension), 1166A>C variant

BCKDHA *(branched chain keto acid dehydrogenase E1, alpha polypeptide)* (eg, maple syrup urine disease, type 1A), Y438N variant

CCR5 *(chemokine C-C motif receptor 5)* (eg, HIV resistance), 32-bp deletion mutation/794 825del32 deletion

81401 - Tier 2; level 2

- **2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat**

  ABL *(c-abl oncogene 1, receptor tyrosine kinase)* (eg, acquired imatinib resistance), T315I variant

  ACADM *(acyl-CoA dehydrogenase, C-4 to C-12 straight chain, MCAD)* (eg, medium chain acyl dehydrogenase deficiency), commons variants (eg, K304E, Y42H)

  ADRB2 *(adrenergic beta-2 receptor surface)* (eg, drug metabolism), common variants (eg, G16R, Q27E)

  AFF2 *(AF4/FMR2 family, member 2 [FMR2])* (eg, fragile X mental retardation 2 [FRAXE]), evaluation to detect abnormal (eg, expanded) alleles

  APOB *(apolipoprotein B)* (eg, familial hypercholesterolemia type B), common variants (eg, R3500Q,R3500W)

  APOE *(apolipoprotein E)* (eg, hyperlipoproteinemia type III, cardiovascular disease, Alzheimer disease), common variants (eg, *2, *3, *4)

  AR *(androgen receptor)* (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), characterization of alleles (eg, expanded size or methylation status)

81402 - Tier 2; level 3

- **>10 SNPs, 2-10 methylated variants, or 2-10 somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene rearrangements, duplication/deletion variants of 1 exon, loss of heterozygosity [LOH], uniparental disomy [UPD]**

Chromosome 18q- (eg, D18S55, D18S58, D18S61, D18S64, and D18S69) (eg, colon cancer), allelicimbalance assessment (ie, loss of heterozygosity)

CYP21A2 *(cytochrome P450, family 21, subfamily A, polypeptide 2)* (eg, congenital adrenalhyperplasia, 21-hydroxylase deficiency), common variants (eg, IVS2-13G, P30L, I172N, exon 6 mutation cluster [I235N, V236E, M238K], V281L, L307FfsX6, Q318X, R356W, P453S, G110VfsX21, 30- kb deletion variant)

ESR1/PGR *(receptor 1/progesterone receptor)* ratio (eg, breast cancer)

IGH@/BCL2 *(t(14;18))* (eg, follicular lymphoma) translocation analysis; major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative

81203 - Tier 2; level 4

- **Analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutationscanning or duplication/deletion variants of 2-5 exons**

Known familial variant not otherwise specified, for gene listed in Tier 1 or Tier 2, DNA sequence analysis, each variant exon

KRAS *(v-Ki-ras2 Kirsten rat sarcoma viral oncogene)* (eg, carcinoma), gene analysis, variant(s) in exon3 (eg, codon 61)

MC4R *(melanocortin 4 receptor)* (eg, obesity), full gene sequence

MICA *(MHC class I polypeptide-related sequence A)* (eg, solid organ transplantation), common variants (eg, *001, *002)

MPL *(myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR)* (eg,myeloproliferative disorder), exon 10 sequence

MT-RNR1 *(mitochondrially encoded 12S RNA)* (eg, nonsyndromic hearing loss), **full gene sequence**

81204 - Tier 2; level 5

- **Analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis**

  ACADS *(acyl-CoA dehydrogenase, C-2 to C-3 short chain*) (eg, short chain acyl-CoA dehydrogenasedeficiency), targeted sequence analysis (eg, exons 5 and 6)

  AFF2 *(AF4/FMR2 family, member 2 [FMR2])* (eg, fragile X mental retardation 2 [FRAXE]),characterization of alleles (eg, expanded size and methylation status)

  AQP2 *(aquaporin 2 [collecting duct])* (eg, nephrogenic diabetes insipidus), full gene sequence

  ARX *(aristaless related homeobox)* (eg, X-linked lissencephaly with ambiguous genitalia, X-linkedmental retardation), full gene sequence

  AVPR2 *(arginine vasopressin receptor 2)* (eg, nephrogenic diabetes insipidus), full gene sequence

81205 - Tier 2; level 6

- **Analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array**

CYP17A1 *(cytochrome P450, family 17, subfamily A, polypeptide 1)* (eg, congenital adrenalhyperplasia), full gene sequence

CYP21A2 *(cytochrome P450, family 21, subfamily A, polypeptide2)* (eg, steroid 21-hydroxylase isoform, congenital adrenal hyperplasia), full gene sequence

Cytogenomic constitutional targeted microarray analysis of chromosome 22q13 by interrogation ofgenomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomalabnormalities

Cytogenomic constitutional targeted microarray analysis of the X chromosome by interrogation ofgenomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities

DBT *(dihydrolipoamide branched chain transacylase E2)* (eg, maple syrup urine disease, type 2),duplication/deletion analysis

81206 - Tier 2; level 7

- **Analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia**

CRB1 *(crumbs homolog 1 [Drosophila])* (eg, Leber congenital amaurosis), full gene sequence

CREBBP *(CREB binding protein)* (eg, Rubinstein-Taybi syndrome), duplication/deletion analysis

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)

DBT *(dihydrolipoamide branched chain transacylase E2)* (eg, maple syrup urine disease, type 2), full gene sequence

81207 - Tier 2; level 8

- **Analysis of 26-50 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of >50 exons, sequence analysis of multiple genes on one platform**

ABCC8 *(ATP-binding cassette, sub-family C [CFTR/MRP], member 8)* (eg, familial hyperinsulinism), fullgene sequence

AGL *(amylo-alpha-1, 6-glucosidase, 4-alpha-glucanotransferase)* (eg, glycogen storage disease typeIII), full gene sequence

AHI1 *(Abelson helper integration site 1)* (eg, Joubert syndrome), full gene sequence

CACNA1A *(calcium channel, voltage-dependent, P/Q type, alpha 1A subunit)* (eg, familial hemiplegicmigraine), full gene sequence

CHD7 *(chromodomain helicase DNA binding protein 7)* (eg, CHARGE syndrome), full gene sequence

COL4A4 *(collagen, type IV, alpha 4)* (eg, Alport syndrome), full gene sequence

81208 - Tier 2; level 9

- **Analysis of >50 exons in a single gene by DNA sequence analysis**

COL4A5 (*collagen, type IV, alpha 5)* (eg, Alport syndrome), full gene sequence

DMD *(dystrophin)* (eg, Duchenne/Becker muscular dystrophy), full gene sequence

DYSF *(dysferlin, limb girdle muscular dystrophy 2B [autosomal recessive])* (eg, limb-girdle muscular dystrophy), full gene sequence

FBN1 *(fibrillin 1)* (eg, Marfan syndrome), full gene sequence

What do you do if your genes/analytes are not listed?

- 81479
- You cannot self assign
- You cannot use multiples of 81479
- Submit a coding change proposal (CCP)

Coding Change Proposal (CCP)

- Form available on AMA website (*www.ama-assn.org/.../doc/**cpt/coding-change**-request-form-mopath.doc*)
- References to document clinical validity
- Clinical vignette
- Description of service

Clinical vignette and description of service

Example: *BRAF* (eg, colorectal carcinoma) gene analysis, V600E variant

Clinical Vignette

- A 54-year-old man with metastatic colorectal carcinoma is being considered for targeted therapy with anti-epidermal growth factor receptor (EGFR) monoclonal antibodies. Initial molecular studies indicate the tumor does not contain any of 12 common *KRAS* mutations at codons 12 or 13. A tumor-rich tissue sample is submitted for *BRAF* gene mutation testing.

Description of Service

- Paraffin is removed, and high quality DNA is isolated from the patient's tumor tissue. DNA is subjected to PCR amplification for exon 15 of the *BRAF* gene. The PCR products undergo bidirectional dideoxynucleotide chain termination sequencing on a capillary electrophoresis instrument. The pathologist or other qualified healthcare professional evaluates the electropherograms to identify nucleotide sequence variants. The pathologist or other qualified healthcare professional composes a report which specifies the patient's mutation status. The report is edited, signed and the results are communicated to appropriate caregivers.

Parameters for Analyte Assignment

- ***In the case of Mendelian and somatic disorders****, there is a demonstrated relationship between biomarker and phenotype (ie, clinical validity)*
- ***Biomarkers (eg, SNPs) that have an association but not a proven causative effect to a known clinical phenotype(s) should have demonstrated clinical usefulness (eg, high positive predictive value, high negative predictive value, directing therapy/management).***
- *At least two U.S. laboratories are performing the analysis, unless proprietary (eg, intellectual property) issues exist*
- The analysis involves ≥ 10 variants identified in unrelated families. Multiple reports of the same variant may be included.
- *For dup/del assessment for Tier 2 code assignment the following guidelines will be used:*
  - *Search GeneTests database. If ≥ 10% of disease alleles are associated with dup/del and ≥ 2 dup/dels are documented, place dup/del for analyte on Tier 2 list or,*
  - *If BIOBASE HGMD® Professional database search identifies ≥ 10% of variants that are associated with dup/del (gross deletion or insertion variants/total number of BIOBASE® variants reported), place dup/del for analyte on Tier 2 list.*

From CCP

Where does NGS/Multi-Gene panels fit?

- AMP submitted a Coding Change Proposal (CCP)
  - Multi-gene panels
  - Quantitative genomic sequence analysis
  - Exome genomic sequence analysis
  - Genome genomic sequence analysis

  - Separates report and interpretation from analytes
  - Provides mechanism for re-analysis

- AMA convened an open meeting for all to discuss
- AMA developed new CPT codes for 2015

NGS/Multi-gene Panels

- **81410:** Aortic Dysfunction
- **81430:** Nonsyndromic Hearing Loss
- **81470:** X-Linked Intellectual Disability
- **81435:** Inherited Colon Cancer
- **81420:** Fetal Chromosomal Aneuploidy
- **81445:** Targeted Neoplastic Genomic Sequence
- **81460:** Whole Mitochondrial
- **81415:** Whole Exome
- **81425:** Whole Genome

www.ama-assn.org

MAAAs

- CMS announced that MAAA codes will be gapfilled if the Medicare contractor determines that the code is payable under the CLFS.

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2014-FinalPayment-Determinations.pdf

Questions

- Why didn’t each gene get its own code?

  Not enough available CPT codes

- Can a code be moved from Tier 2 to Tier 1

  Yes; has to be requested by a Coding Change Proposal and approved by the AMA

REIMBURSEMENT

Physician fee schedule (PFS) vs. Clinical lab fee schedule (CLFS)

- Background

  Molecular “stacking” codes were on CLFS

  The RUC recommended PFS

  - Specialty Society Relative Value Update Committee (RUC) = AMA multi-specialty committee tasked with making relative value recommendations to CMS for new and revised codes, as well as annually updating relative value units (RVUs) to reflect changes in medical practice

  Federal laws related to physician practice

  - MD vs PhD
  - Copays
  - Anti kickback rules
  - Physician signature requirements

- CMS placed all new Tier 1 and Tier 2 codes on CLFS

PFS vs. CLFS – Physician practice

- *42 CFR 415.130 Physician pathology services.* The carrier pays for pathology services furnished by a physician to an individual beneficiary on a fee schedule basis only if the services meet the conditions for payment in § 415.102(a)* and are one of the following services:
  (1) Surgical pathology services.
  (2) Specific cytopathology, hematology, and blood banking services that have been identified to require performance by a physician and are listed in program operating instructions.
  (3) Clinical consultation services that meet the requirements in paragraph (c) of this section.
  (4) Clinical laboratory interpretative services that meet the requirements of paragraphs (C)(1), (c)(3), and (c)(4) of this section and that are specifically listed in program operating instructions.

    - * 415.102(a) requires the services be ordinarily performed by a physician and directly contribute to the diagnosis of an individual patient.

PFS vs. CLFS – other requirements

- Placement of MolPath CPT codes on PFS:
  - Labs would have to collect 20% copays
  - Special signature rules not required of clinical laboratory tests, and
  - Medicare policies regarding physician kickbacks and purchased test rules different than those for clinical laboratory tests, and
  - Pathology tests are paid on a different, and much lower fee schedule, in the Medicare Hospital Outpatient setting, whereas clinical laboratory tests are paid on the same clinical laboratory fee schedule in this setting.
  - Indirect costs would be assigned on the basis of all pathologist indirect costs, including hospital-based pathologists and the mean indirect costs of pathology tests, dominated by the routine preparation of paraffin blocks and slides. These indirect costs likely far below the indirect expense of a molecular diagnostics center, with far more expensive staff, development, and QC costs.

Coding for Physician Interpretation and Reporting

- CMS created Healthcare Common Procedure Coding System (HCPCS) code G0452 *(Molecular pathology procedure; physician interpretation and report)* effective Jan 1, 2013
- This code allows physicians (MDs) to bill for interpretation and reporting services that go beyond the technical reporting of test results
- The code CANNOT be billed by non-physician geneticists or other lab personnel

  The rates established for the Tier 1 and Tier 2 codes are meant to account for work performed by non-physician personnel, including PhD-certified geneticists
- In 2013, this code is reimbursed at $18.71 under the Medicare Physician Fee Schedule (MPFS)

2 methods for CMS to determine reimbursement

- Crosswalk
- Gapfill

Crosswalking

- If test is comparable to an existing test
- CMS sets reimbursement of new test to existing test
- Assigned a local fee and corresponding National Limitation Amount (NLA)

Gapfilling

- CMS determines no adequate comparable
- Medicare carriers are instructed to Gapfill
  - Empirical process based on local pricing patterns
  - Medical Directors may meet and share information regarding the new test, though cannot reach a formal consensus.
- Approximate Timeline
  - April 30 - CMS posted interim contractor-specific amounts online
  - 60-day comment period on interim amounts (May-June)
  - CMS posts final contractor-specific amounts and National Limitation Amounts (NLA) online
    - CMS sets the NLA for each CPT code at the median of the contractor specific amounts
  - Reconsideration requests accepted for 30 days
  - Final NLAs made effective January 1 for the entire country

CMS posted Gapfill rates Tier1

HCPCS	Descriptor	Modifier	National Limit	Mid Point
81206	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative		$ 225.38	$ 225.38
81207	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative		$ 199.08	$ 199.08
81208	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative		$ 221.09	$ 221.09
81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant		$ 180.60	$ 180.60
81211	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)		$ 2,795.09	$ 2,795.09
81212	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants		$ 178.04	$ 178.04
81213	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants		$ 587.12	$ 587.12
81214	BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)		$ 1,449.01	$ 1,449.01
81215	BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant		$ 93.94	$ 93.94
81217	BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant		$ 93.94	$ 93.94
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)		$ 294.00	$ 294.00
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)		$ 455.00	$ 455.00
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)		$ 176.40	$ 176.40

Gapfill rates, con't

HCPCS	Descriptor	National Limit	Mid Point
81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis; common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	$ 332.50	$ 332.50
81240	F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis; 20210G>A variant	$ 67.64	$ 67.64
81241	F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis; Leiden variant	$ 84.00	$ 84.00
81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis, internal tandem duplication (ITD) variants (ie, exons 14, 15)	$ 167.17	$ 167.17
81256	HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis; common variants (eg, C282Y, H63D)	$ 89.84	$ 89.84
81261	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (eg, polymerase chain reaction)	$ 272.15	$ 272.15
81262	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas), gene rearrangement analysis to detect abnormal clonal population(s); direct probe methodology (eg, Southern blot)	$ 60.00	$ 60.00
81263	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma), variable region somatic mutation analysis	$ 404.83	$ 404.83
81264	IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)	$ 205.26	$ 205.26
81265	Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)	$ 295.60	$ 295.60
81267	Chimerism (engraftment) analysis, post hematopoietic stem cell transplantation specimen, includes comparison to previously performed baseline analyses; without cell selection	$ 285.17	$ 285.17
81268	Chimerism (engraftment) analysis, post hematopoietic stem cell transplantation specimen, includes comparison to previously performed baseline analyses; with cell selection (eg, CD3, CD33), each cell type	$ 358.47	$ 358.47
81270	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant	$ 126.00	$ 126.00
81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13	$ 198.97	$ 198.97

Gapfill rates, con't

HCPCS	Descriptor	National Limit	Mid Point
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis; common variants (eg, 677T, 1298C)	$ 60.00	$ 60.00
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	$ 651.12	$ 651.12
81293	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	$ 261.02	$ 261.02
81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	$ 192.12	$ 192.12
81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	$ 152.86	$ 152.86
81296	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	$ 130.51	$ 130.51
81297	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	$ 152.86	$ 152.86
81298	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	$ 290.01	$ 290.01
81299	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	$ 162.46	$ 162.46
81300	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	$ 162.90	$ 162.90
81301	Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed	$ 398.03	$ 398.03
81310	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants	$ 249.01	$ 249.01

Gapfill rates, con't

HCPCS	Descriptor	National Limit	Mid Point
81315	PML/RARalpha, (t(15;17)), (PML-RARA regulated adaptor molecule 1) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative	$ 284.97	$ 284.97
81316	PML/RARalpha, (t(15;17)), (PML-RARA regulated adaptor molecule 1) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative	$ 434.65	$ 434.65
81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	$ 787.19	$ 787.19
81318	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	$ 186.01	$ 186.01
81319	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants	$ 223.34	$ 223.34
81321	PTEN (phosphate and tensin homolog) (eg, Cowden syndrome, PTEN harmatoma tumor syndrome) gene analysis; full gene sequence	$ 605.24	$ 605.24
81322	PTEN (phosphate and tensin homolog) (eg, Cowden syndrome, PTEN harmatoma tumor syndrome) gene analysis; known familial variants	$ 58.84	$ 58.84
81323	PTEN (phosphate and tensin homolog) (eg, Cowden syndrome, PTEN harmatoma tumor syndrome) gene analysis; duplication/deletion variants	$ 88.26	$ 88.26
81332	SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z)	$ 60.00	$ 60.00
81340	TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction)	$ 287.17	$ 287.17
81341	TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (eg, Southern blot)	$ 68.16	$ 68.16
81342	TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)	$ 276.98	$ 276.98

Gapfill rates, con't

HCPCS	Descriptor	National Limit	Mid Point
81370	HLA Class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1	$ 552.75	$ 552.75
81371	HLA Class I and II typing, low resolution (eg, antigen equivalents); HLA-A, -B, and -DRB1 (eg, verification typing)	$ 330.84	$ 330.84
81372	HLA Class I typing, low resolution (eg, antigen equivalents); complete (ie, HLA-A, -B, and -C)	$ 303.64	$ 303.64
81373	HLA Class I typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-A, -B, or -C), each	$ 153.08	$ 153.08
81374	HLA Class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, B*27), each	$ 100.00	$ 100.00
81375	HLA Class II typing, low resolution (eg, antigen equivalents); HLA-DRB1/3/4/5 and -DQB1	$ 303.43	$ 303.43
81376	HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB/3/4/5,-DQB1, -DQA1, -DPB1, or -DPA1), each	$ 168.00	$ 168.00
81377	HLA Class II typing, low resolution (eg, antigen equivalents); one antigen equivalent, each	$ 126.20	$ 126.20
81378	HLA Class I and II typing, high resolution (ie, alleles or allele groups), HLA-A, -B, -C, and -DRB1	$ 475.00	$ 475.00
81379	HLA Class I typing, high resolution (ie, alleles or allele groups); complete (ie, HLA-A, -B, and -C)	$ 461.00	$ 461.00
81380	HLA Class I typing, high resolution (ie, alleles or allele groups); one locus (eg, HLA-A, -B, or -C), each	$ 243.64	$ 243.64
81381	HLA Class I typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, B*57:01P), each	$ 130.00	$ 130.00
81382	HLA Class II typing, high resolution (ie, alleles or allele groups,); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each	$ 170.00	$ 170.00
81383	HLA Class II typing, high resolution (ie, alleles or allele groups,); one allele or allele group (eg, HLA-DQB1*06:02P), each	$ 150.00	$ 150.00

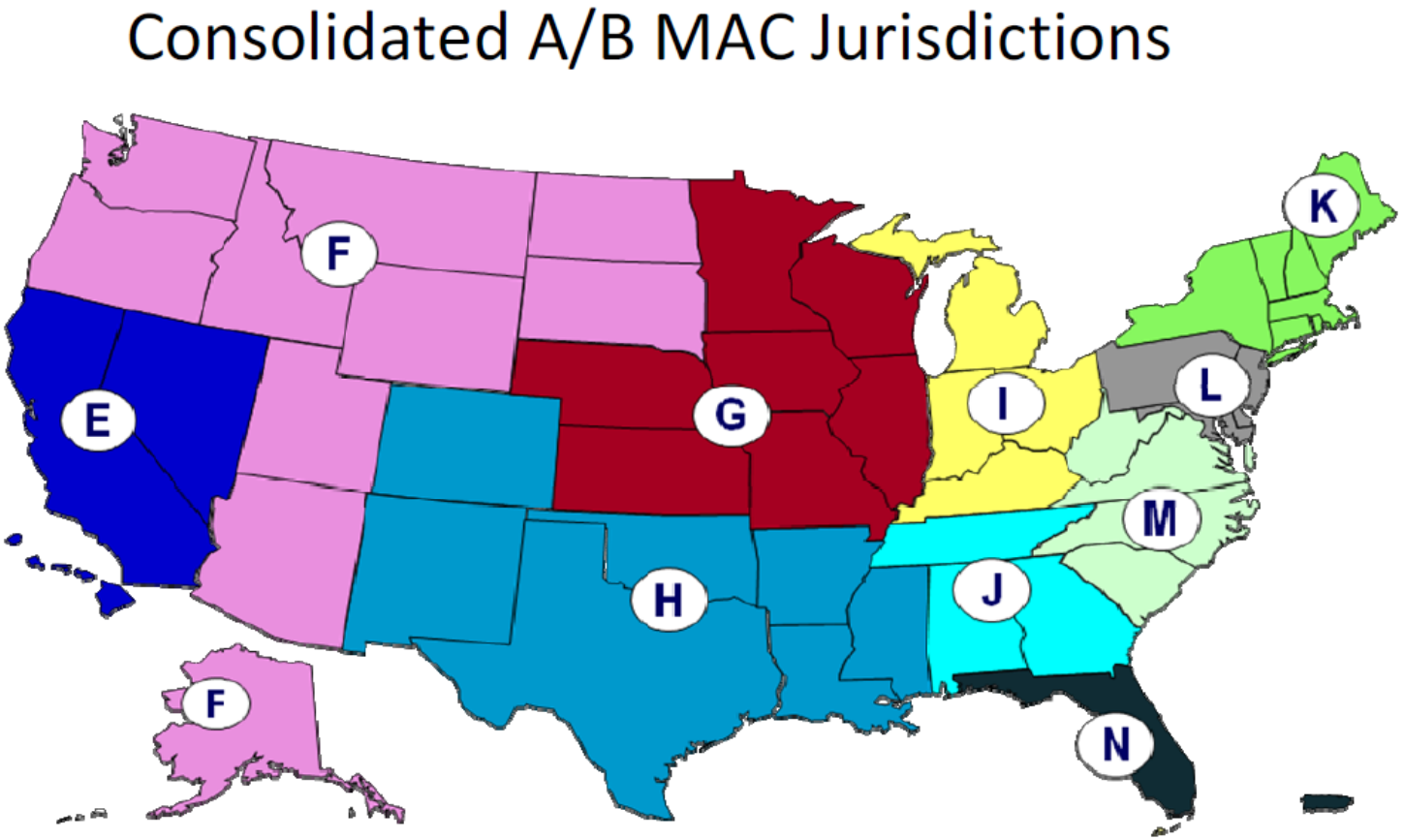
Genomic sequencing procedure (GSPs) codes

- CMS to Gap-fill
- Similar process to MolPath
- Final reimbursement expected in late summer 2015

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html

Medicare Administrative Contractors (MACs)

E Noridian
F Noridian
H Novitas
L Novitas
K NGS
G NGS
N First Coast
J Cahaba
M Palmetto
I WPS



http://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MACJurisdictions.html

Proposed MAC Gapfill Rates

- Many of the MACs appear to have coordinated on their proposed gap-fill rates for MolPath
- Although some MACs (such as Palmetto) established payment rates for individual analytes assigned to each Tier 2 code, CMS did not include them in their release (http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Covered%20Tests~9BMLRK6738?open&navmenu=Browse^By^Topic||||)
- CMS hasn't finalized reimbursement levels for any Tier 2 codes

  MACs will continue to establish pricing for tests that fall in this coding category.

Summary

- The complete revision of the MolPath CPTs has had a huge impact on reimbursement for molecular pathology assays