



*2018 Laboratory and Pathology
Coding, Billing &
Reimbursement Update*

Lab Institute

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Presented by

Diana W. Voorhees, M.A.
CLS, MT, SH, CPCO
Principal/CEO
DV & Associates, Inc.
dvassoc@aol.com
801.424.5274

Objectives

- Discuss procedural coding changes for 2018
- Describe proposed changes in government reimbursement
- Discuss pertinent policies and issues affecting coverage
- Determine anticipated impact of CMS editing systems
- As time allows, delve into additional topics of interest or concern



CLFS and PAMA

Protecting Access to Medicare Act (PAMA)

- ▶ On September 22, 2017, the Centers for Medicare and Medicaid Services (CMS) released its proposed new payment rates for laboratory tests included in the CLFS.
- ▶ Under PAMA, CMS is required to rebase payments under the CLFS to reflect private sector rates.
- ▶ The CMS proposal indicated that 75 percent of all codes on the Healthcare Common Procedure Coding System (HCPCS) would realize payment reductions in 2018.
- ▶ CMS further estimated that these cuts would reduce overall Medicare spending for laboratory testing by nearly 11 percent or \$670 million in 2018.

PAMA Questionable Analysis

- ▶ According to the CMS:
 - ▶ 90 percent of the test payment data came from independent laboratories
 - ▶ Represent 5% of all US laboratories
 - ▶ 9 percent came from physician office laboratories and hospitals,
 - ▶ POLs and hospitals reportedly represent more than 43 percent of Medicare Part B lab payments.
 - ▶ Services usually associated with higher payment levels
 - ▶ 1.85 percent of data was collected from laboratories serving rural areas

PAMA Questionable Analysis

- ▶ Of note:
 - ▶ The Senate Appropriations Committee recently forwarded report language regarding the Labor, Health and Human Services funding bill
 - ▶ Urged CMS to work with stakeholders to ensure that the new CLFS rates represent "the full spectrum of laboratories, including hospital, independent, and physician office laboratories"



PAMA Questionable Analysis

- ▶ At present:
 - ▶ Over ten years, the cuts may total as much as \$13 billion, which is more than three times the estimate of \$3.9 billion Congress originally anticipated.
 - ▶ Laboratory Industry questioning *adequacy* of data gathered and thus, the *accuracy* of the analytic process to report *reliable* weighted medians for individual procedural codes



Molecular Pathology Testing



Tier 1 Codes

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81175 ASXL1; full gene sequence
 - ▶ Xwalk 81295 (MSH2)
 - ▶ 2017 NLA \$152.54 2018 WM \$381.70
- ▶ 81176 ASXL1; targeted sequence analysis (eg, exon 12)
 - ▶ Xwalk 81272 (KIT)
 - ▶ 2017 NLA \$331.82 2018 WM \$329.51

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81230 CYP3A4, common variant(s) (eg, *2, *22)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81
- ▶ 81231 CYP3A5, common variants (eg, *2, *3, *4, *5 *6, *7)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81

New Codes – Preliminary - Molecular Pathology Testing

- *CPT Procedure*
- 81232 DPYD, common variant(s) (eg, *2A, *4, *5, *6)
 - Xwalk 81227 (CYP2c9)
 - 2017 NLA \$176.03 2018 WM \$174.81
- 81238 F9 full gene sequence
 - Xwalk 81295 (MSH2)
 - 2017 NLA \$152.54 2018 WM \$381.70

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81247 G6PD; common variant(s) (eg, A, A-)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81
- ▶ 81248 G6PD; known familial variant(s)
 - ▶ Xwalk 81322 (PTEN)
 - ▶ 2017 NLA \$58.72 2018 WM \$46.60 (\$52.85)
- ▶ 81249 G6PD; full gene sequence
 - ▶ Xwalk 81295 (MSH2)
 - ▶ 2017 NLA \$152.54 2018 WM \$381.70

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81258 HBA1/HBA2; known familial variant
 - ▶ Xwalk 81322 (PTEN)
 - ▶ 2017 NLA \$58.72 2018 WM \$46.60 (\$52.85)
- ▶ 81259 HBA1/HBA2; full gene sequence
 - ▶ Xwalk 81295 (MSH2)
 - ▶ 2017 NLA \$152.54 2018 WM \$381.70
- ▶ 81269 HBA1/HBA2; duplication/deletion variants
 - ▶ Xwalk 81294 (MLH1)
 - ▶ 2017 NLA \$191.72 2018 WM \$202.40

New Codes – Preliminary - Molecular Pathology Testing

- *CPT Procedure*
- 81105 Human Platelet Antigen 1 genotyping (HPA-1), common variant, HPA-1a/b (L33P)
 - Xwalk 81227 (CYP2c9)
 - 2017 NLA \$176.03 2018 WM \$174.81
- 81106 Human Platelet Antigen 2 genotyping (HPA-2), common variant, HPA-2a/b (T145M)
 - Xwalk 81227 (CYP2c9)
 - 2017 NLA \$176.03 2018 WM \$174.81

New Codes – Preliminary - Molecular Pathology Testing

- *CPT Procedure*
- 81107 Human Platelet Antigen 3 genotyping (HPA-3), common variant, HPA-3a/b (I843S)
 - Xwalk 81227 (CYP2c9)
 - 2017 NLA \$176.03 2018 WM \$174.81
- 81108 Human Platelet Antigen 4 genotyping (HPA-4), common variant, HPA-4a/b (R143Q)
 - Xwalk 81227 (CYP2c9)
 - 2017 NLA \$176.03 2018 WM \$174.81

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81109 Human Platelet Antigen 5 genotyping (HPA-5), common variant eg, HPA-5a/b (K505E)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81
- ▶ 81110 Human Platelet Antigen 6 genotyping (HPA-6w, common variant, HPA-6a/b (R489Q))
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81111 Human Platelet Antigen 9 genotyping (HPA-9w, common variant, HPA-9a/b (V837M))
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81
- ▶ 81112 Human Platelet Antigen 15 genotyping (HPA-15), common variant, HPA-15a/b (S682Y))
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81

New Codes – Preliminary - Molecular Pathology Testing

- *CPT Procedure*
- 81120 IDH1 (isocitrate dehydrogenase 1 [NADP+], common variants (eg, R132H, R132C)
 - Xwalk 81227 (CYP2c9)
 - 2017 NLA \$176.03 2018 WM \$174.81
- 81121 IDH2 (isocitrate dehydrogenase 2 [NADP+], common variants (eg, R140W, R172M)
 - Xwalk 81227 (CYP2c9)
 - 2017 NLA \$176.03 2018 WM \$174.81

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81283 IFNL3 gene analysis, rs12979860 variant
 - ▶ Xwalk 81322 (PTEN)
 - ▶ 2017 NLA \$58.72 2018 WM \$46.60 (\$52.85)
- ▶ 81334 RUNX1, targeted sequence analysis (eg, exons 3-8)
 - ▶ Xwalk 81272 (KIT)
 - ▶ 2017 NLA \$331.82 2018 WM \$329.51

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81328 SLCO1B1, common variant(s) (eg, *5)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81
- ▶ 81335 TPMT, common variants (eg, *2, *3)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81346 TYMS, common variant(s) (eg, tandem repeat variant)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81
- ▶ 81361 HBB; common variant(s) (eg, HbS, HbC, HbE)
 - ▶ Xwalk 81227 (CYP2c9)
 - ▶ 2017 NLA \$176.03 2018 WM \$174.81
- ▶ 81362 HBB; known familial variant(s)
 - ▶ Xwalk 81322 (PTEN)
 - ▶ 2017 NLA \$58.72 2018 WM \$46.60 (\$52.85)

New Codes – Preliminary - Molecular Pathology Testing

- ▶ *CPT Procedure*
- ▶ 81363 HBB; duplication/deletion variant(s)
 - ▶ Xwalk 81294 (MLH1)
 - ▶ 2017 NLA \$191.72 2018 WM \$202.40
- ▶ 81364 HBB; full gene sequence
 - ▶ Xwalk 81295 (MSH2)
 - ▶ 2017 NLA \$152.54 2018 WM \$381.70

New Codes – Preliminary – Genomic Sequence Testing

- ▶ *CPT Procedure*
- ▶ 81448 Hereditary peripheral neuropathies panel (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, and SPTLC1)
 - ▶ Xwalk 81445 (Targeted genomic sequence panel, neoplasm, 5-50 genes)
 - ▶ 2017 NLA \$602.10 2018 WM \$597.91

Description Changes - Preliminary Genomic Sequence Testing

- ▶ *CPT Procedure*
- ▶ 81432 Hereditary breast cancer related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10-14 genes, *always* including ~~ATM~~, BRCA1, BRCA2, ~~BRIP1~~, CDH1, MLH1, MSH2, MSH6, ~~NBN~~, PALB2, PTEN, ~~RAD51G~~, STK11 and TP53

Description Changes - Preliminary Genomic Sequence Testing

- ▶ *CPT Procedure*
- ▶ 81439 ~~Inherited~~ Hereditary cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 ~~cardiomyopathy-related~~ genes, ~~including~~ (eg, DSG2, MYBPC3, MYH7, PKP2, ~~and~~ TTN)

New Codes – Preliminary – Multianalyte Assays with Algorithmic Analyses

- ▶ *CPT Procedure*
- ▶ 81520 Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
 - ▶ Xwalk 81528 (Colorectal screen, 10 DNA markers + fecal Hgb, +/-)
 - ▶ 2017 NLA \$512.43 2018 WM \$508.87

New Codes – Preliminary – Multianalyte Assays with Algorithmic Analyses

- ▶ *CPT Procedure*
- ▶ 81521 Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis
 - ▶ Xwalk 81528 (Colorectal screen, 10 DNA markers + fecal Hgb, +/-)
 - ▶ 2017 NLA \$512.43 2018 WM \$508.87

New Codes – Preliminary – Multianalyte Assays with Algorithmic Analyses

- ▶ *CPT Procedure*
- ▶ 81541 Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a disease-specific mortality risk score
 - ▶ Xwalk 81528 (Colorectal screen, 10 DNA markers + fecal Hgb, +/-)
 - ▶ 2017 NLA \$512.43 2018 WM \$508.87

New Codes – Preliminary – Multianalyte Assays with Algorithmic Analyses

- ▶ *CPT Procedure*
- ▶ *81551* Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy
- ▶ Xwalk 81528 (Colorectal screen, 10 DNA markers + fecal Hgb, +/-)
- ▶ 2017 NLA \$512.43 2018 WM \$508.87



Tier 2 Changes

Tier 2 Changes

- ▶ CPT 81400 Deletions:

- ▶ DPYD HPA1 HPA2 HPA3 HPA4 HP5
- ▶ HPA6w HPA9w HPA15 IL28B SLCO1B1

- ▶ CPT 81401 Deletions:

- ▶ CYP3A4 CYP3A5 HBB TPMT TYMS

- ▶ CPT 81401 Additions:

- ▶ LINC00518 (long intergenic non-protein coding RNA 518) (eg, melanoma), expression analysis
- ▶ PRAME (preferentially expressed antigen in melanoma) (eg, melanoma), expression analysis

Tier 2 Changes

- ▶ CPT 81403 Deletions:
 - ▶ HBB IDH1 IDH2
- ▶ CPT 81404 Deletions:
 - ▶ HBA1/HBA2 HBB fgs
- ▶ CPT 81405 Deletions:
 - ▶ F9 HBA1/HBA2 fgs

Tier 2 Changes

- ▶ CPT 81405 Additions:
 - ▶ CPOX (coproporphyrinogen oxidase) (eg, hereditary coproporphyria), full gene sequence
 - ▶ CTRC (chymotrypsin C) (eg, hereditary pancreatitis), full gene sequence
 - ▶ PKLR (pyruvate kinase, liver and RBC) (eg, pyruvate kinase deficiency), full gene sequence

Tier 2 Changes

- ▶ CPT 81406 Additions:
 - ▶ HMBS (hydroxymethylbilane synthase) (eg, acute intermittent porphyria), full gene sequence
 - ▶ PPOX (protoporphyrinogen oxidase) (eg, variegate porphyria), full gene sequence
- ▶ CPT 81406 Description Change:
 - ▶ ANOS1 ~~KAL1~~ (anosmin-1 ~~Kallmann syndrome 1~~ **sequence**) (eg, Kallmann syndrome 1), full gene sequence

Tier 2 Weighted Medians

<i>CPT</i>	<i>WM 2018</i>	<i>Palmetto 2017</i>	<i>Palmetto Average</i>
81400	\$63.96	\$55.23 – 185.84	\$73.31
81401	\$137.00	\$54.19 – 278.18	\$129.29
81402	\$150.33	\$89.04 – 98.13	\$93.59
81403	\$185.20	\$67.10 – 303.03	\$110.12
81404	\$274.83	\$94.97 – 639.96	\$300.97
81405	\$301.35	\$278.18 – 426.32	\$361.32
81406	\$282.88	\$384.52	\$384.51
81407	\$846.27	NA	NA
81408	\$2,000.00	NA	NA

Immunology Testing

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New Codes – Preliminary - Immunology Testing

- *CPT Procedure*
- 86008 Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
 - Xwalk 86003 (Allergen specific IGE, each)
 - 2017 NLA \$7.16 2018 WM \$4.65 (\$6.44)
- 86794 Zika virus, IgM
 - Xwalk 86788 (West Nile antibody, IGM))
 - 2017 NLA \$23.11 2018 WM \$14.47 (\$20.80)



Microbiology Testing

New Codes – Preliminary - Microbiology Testing

- ▶ *CPT Procedure*
- ▶ 87634 Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique
 - ▶ Xwalk 87798 (Infectious agent DNA/RNA, NOS)
 - ▶ 2017 NLA \$48.14 2018 WM \$29.83 (\$43.33)
- ▶ 87662 Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique
 - ▶ Xwalk 87798 (Infectious agent DNA/RNA, NOS)
 - ▶ 2017 NLA \$48.14 2018 WM \$29.83 (\$43.33)



Proprietary Laboratory Analyses

Proprietary Laboratory Analyses (PLA)

- ▶ Proprietary Laboratory Analyses (PLA) codes are a new addition to the CPT® code set approved by the AMA CPT® Editorial Panel.
- ▶ They are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test.
- ▶ Tests with PLA codes must be performed on human specimens and must be requested by the clinical laboratory or the manufacturer that offers the test.

Proprietary Laboratory Analyses (PLA)

- ▶ The PLA code section includes (but is not limited to) Advanced Diagnostic Laboratory Tests (ADLTs) and Clinical Diagnostic Laboratory Tests (CDLTs) as defined under the Protecting Access to Medicare Act of 2014 (PAMA).
- ▶ Proprietary laboratory analyses (PLA) codes describe proprietary clinical laboratory analyses and can be either provided by a single (“sole-source”) laboratory or licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration [FDA]).

Proprietary Laboratory Analyses (PLA)

- ▶ PLA test codes will be released and posted online on a quarterly basis (fall, winter, spring and summer) in data files.
 - ▶ New codes are effective the quarter following their publication.
 - ▶ These codes will also be included in the annual update of the CPT codebook beginning in 2018.

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0001U Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported
 - ▶ PreciseType® HEA Test
 - ▶ Immucor, Inc.
 - ▶ Xwalk 81403 recommended but code is carrier priced
 - ▶ CMS decision to gapfil

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0002U Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps
 - ▶ PolypDX™
 - ▶ Atlantic Diagnostic Laboratories, LLC
 - ▶ Metabolomic Technologies Inc
 - ▶ Xwalk 83789 (MS)
 - ▶ 2017 NLA \$24.77 2018 WM \$24.11

New Codes - Proprietary Laboratory Analyses

- *CPT Procedure*
- 0003U Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score
 - Overa (OVA1 Next Generation)
 - Aspira Labs, Inc.
 - Vermillion, Inc.
 - Xwalk 1.25x 81539 (prostate cancer)
 - 2017 NLA \$752.63 2018 WM None

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0004U Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate
 - ▶ Gram-Negative Bacterial Resistance Gene PCR Panel
 - ▶ Mayo Clinic
 - ▶ Check-Points Health BV, Wageningen, Netherlands
 - ▶ Xwalk 87798 (Infectious agent DNA/RNA, NOS)
 - ▶ 2017 NLA \$48.14 2018 WM \$29.83 (\$43.33)

New Codes - Proprietary Laboratory Analyses

- *CPT Procedure*
- 0005U Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score
 - ExosomeDx® Prostate (IntelliScore)
 - Exosome Diagnostics, Inc.
 - Xwalk 81528 (Colorectal screen, 10 DNA markers + fecal Hgb, +/-)
 - 2017 NLA \$512.43 2018 WM \$508.87

New Codes - Proprietary Laboratory Analyses

- *CPT Procedure*
- 0006U Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service
 - Aegis Drug-Drug Interaction Test
 - Aegis Sciences Corporation
 - Xwalk G0483 (Drug testing)
 - 2017 NLA \$253.87 2018 WM \$193.71 (\$228.48)

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0007U Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service
 - ▶ ToxProtect
 - ▶ Genotox Laboratories LTD
 - ▶ Xwalk 0.5x 80307 + 0.5x G0480 (Drug testing presumptive & definitive)
 - ▶ 2017 NLA \$ 39.91 + \$ 58.83 2018 WM None + \$23.98

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0008U Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin
 - ▶ AmHPR Helicobacter pylori Antibiotic Resistance Next Generation Sequencing Panel
 - ▶ American Molecular Laboratories, Inc.
 - ▶ Xwalk 81445 (Targeted genomic sequence panel, neoplasm, 5-50 genes)
 - ▶ 2017 NLA \$602.10 2018 WM \$597.91

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0009U Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified
 - ▶ DEPAarray™ HER2
 - ▶ PacificDx
 - ▶ Xwalk 86320 (Serun IE)
 - ▶ 2017 NLA \$30.75 2018 WM \$29.92

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0010U Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate
 - ▶ Bacterial Typing by Whole Genome Sequencing
 - ▶ Mayo Clinic
 - ▶ Xwalk 87153 (Culture typing sequence)
 - ▶ 2017 NLA \$158.24 2018 WM \$114.00 (\$142.42)

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0011U Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites
 - ▶ Cordant CORE™
 - ▶ Cordant Health Solutions
 - ▶ Xwalk G0480 (Drug testing)
 - ▶ 2017 NLA \$ 117.65 2018 WM \$47.96 (\$105.89)

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0012U Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)
 - ▶ MatePair Targeted Rearrangements, Congenital
 - ▶ Mayo Clinic
 - ▶ Xwalk 81445 (Targeted genomic sequence panel, neoplasm, 5-50 genes)
 - ▶ 2017 NLA \$602.10 2018 WM \$597.91

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0013U Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)
 - ▶ MatePair Targeted Rearrangements, Oncology
 - ▶ Mayo Clinic
 - ▶ Xwalk 81445 (Targeted genomic sequence panel, neoplasm, 5-50 genes)
 - ▶ 2017 NLA \$602.10 2018 WM \$597.91

New Codes - Proprietary Laboratory Analyses

- *CPT Procedure*
- 0014U Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)
 - MatePair Targeted Rearrangements, Hematologic
 - Mayo Clinic
 - Xwalk 81445 (Targeted genomic sequence panel, neoplasm, 5-50 genes)
 - 2017 NLA \$602.10 2018 WM \$597.91

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0015U Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support
 - ▶ OneOme RightMed Pharmacogenomic Test
 - ▶ OneOme, LLC
 - ▶ Xwalk 81528 (Colorectal screen, 10 DNA markers + fecal Hgb, +/-)
 - ▶ 2017 NLA \$512.43 2018 WM \$508.87

New Codes - Proprietary Laboratory Analyses

- *CPT Procedure*
- 0016U Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation
 - BCR-ABL1 major and minor breakpoint fusion transcripts
 - University of Iowa, Department of Pathology,
 - Asuragen
 - Xwalk 81206 (BCR/ABL)
 - 2017 NLA \$224.91 2018 WM \$116.03 (\$202.42)

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0017U Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected
 - ▶ JAK2 Mutation
 - ▶ University of Iowa, Department of Pathology
 - ▶ Xwalk 81270 (JAK2)
 - ▶ 2017 NLA \$ 125.74 2018 WM \$77.54 (\$113.17)

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0018U Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy
 - ▶ ThyraMIR
 - ▶ Interpace Diagnostics
 - ▶ Interpace Diagnostics
 - ▶ Implemented in October – No information from CMS

New Codes - Proprietary Laboratory Analyses

- ▶ *CPT Procedure*
- ▶ 0019U Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents
 - ▶ OncoTarget/ OncoTreat
 - ▶ Columbia University Department of Pathology and Cell Biology
 - ▶ Darwin Health
 - ▶ Implemented in October – No information from CMS



Additional New Codes

New Category III Codes

- *CPT Procedure*
- 0500T Infectious agent detection by nucleic acid (DNA or RNA), Human Papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (ie, genotyping)
 - ▶ (For reporting four or fewer separately reported high-risk HPV types, see 87624, 87625) ◀
 - ▶ (For reporting of separately reported high-risk HPV types 16, 18 and 45, if performed, use 87625) ◀
 - ▶ (Do not report 0500T in conjunction with 87624 or 87625 for the same procedure) ◀
- No other information announced

New CMS “G” Code

- *CPT Procedure*
- G0499 Hepatitis B screening in non-pregnant, high risk individual includes hepatitis B surface antigen (HBsAg) followed by a neutralizing confirmatory test for initially reactive results, and antibodies to HBsAg (anti-HBs) and hepatitis B core antigen (anti-HBc)
 - Xwalk 87340 (HCsAg) + 0.05x 87341(HBsAG neutralization) + 86704 (HBcAb) + 86706 (HBsAb)
 - 2017 NLA \$14.17 + \$ 0.71 + \$16.53 + \$14.73
 - 2018 WM \$ 9.20 + \$0.46 + \$10.66 + 9.41
 - 2018 Cap = \$12.75 + \$0.64 + \$14.88 + \$13.26 = \$41.53



Reconsidered Test Codes

Newly Reconsidered Codes

- ▶ *CPT* *Procedure*
- ▶ 81327 SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis
 - ▶ Request Xwalk to 81288 (MLH1)
 - ▶ CMS retaining Xwalk 81287 (MGMT)



2017 New Codes With No Information for Weighted Medium

2017 Codes With No Data


- *CPT Procedure* *Xwalk*
- 80305 Drug testing, direct optical observation G0477
 - Maintain 2016
- 80306 Drug testing, instrument assisted G0478
 - Maintain 2016
- 80307 Drug testing, instrument analyzed G0479
 - Maintain 2016
- 81413 Cardiac ion channelopathies 81435
 - Maintain 2016

2017 Codes With No Data

- *CPT Procedure* *Xwalk*
- 81414 Cardiac ion channelopathies, min 2 genes 81436
 - Maintain 2016
- 81422 Fetal microdeletions 81436
- 81439 Inherited cardiomyopathy 81435
 - Maintain 2016
- 81539 Prostate assay of 4 genes None
 - Keep gapfill from 2016
- 84410 Testosterone, bioavailable 84402
 - Maintain 2016 + 84403

2017 Codes With No Data

- ▶ *CPT Procedure* *Xwalk*
- ▶ 87483 Infectious agent panel 87633
 - ▶ Maintain 2016
- ▶ G0475 HIV agent/antibody screening 87389
 - ▶ Maintain 2016
- ▶ G0476 HPV high risk 87624
 - ▶ Maintain 2016
- ▶ G0659 Drug test, definitive (POL) 80307
 - ▶ Maintain 2016



Other Codes With No Information for Weighted Medium

Other Codes With No Data

<i>CPT</i>	<i>Procedure</i>	<i>Xwalk</i>
▶ 80410	Calcitonin Stimulation panel	82308x3
▶ 80418	Pituitary panel	82024x4
▶ 80435	Insulin tolerance	82947x5
		+83003x5
▶ 81316	PML/RARA	81206
▶ 81326	PMP22	81322
▶ 81425	Genome sequence	81445
▶ 81426	Genome sequence comparator	81445
▶ 81427	Genome sequence, reevaluation	81445x0.5

Other Codes With No Data

<i>CPT Procedure</i>	<i>Xwalk</i>
81434 Retinal pigmentosa	81432
81470 X-linked disability	81445
81471 X-linked disability	81433
81506 Endocrinology, 7 analytes	82728
82286 Bradykinin	82310
82387 Cathspin-d	82373
82759 Galactokinase, RBC	82775
82979 Glutathione reductase	82977

Other Codes With No Data

<i>CPT</i>	<i>Procedure</i>	<i>Xwalk</i>
83662	Fetal Lung stability, foam	83663
83857	Methemealbumin	84165
83987	pH, breath	82075
84085	Phospjogluconate	82977
84485	Trypsin	82977
84577	Urobilinogen, feces	82710
84580	Urobilinogen, urine	82615

Other Codes With No Data

➤ <i>CPT Procedure</i>	<i>Xwalk</i>
➤ <i>85170 Clot retraction</i>	<i>85175x0.8</i>
➤ <i>85337 Thrombomodulum</i>	<i>85300</i>
➤ <i>85400 Fibrinolytic factors/inhibitors</i>	<i>85410</i>
➤ <i>85530 Heparine-protamine</i>	<i>85520</i>
➤ <i>86327 IEP, crossed</i>	<i>86320</i>
➤ <i>86729 Lymphogranuloma antibody</i>	<i>86632</i>
➤ <i>86821 HLA typing, lymph culture</i>	<i>86822</i>

Other Codes With No Data

➤	<i>CPT Procedure</i>	<i>Xwalk</i>
➤	86829 HLA antibody	86822
➤	87152 Culture typing	87158
➤	87267 Enterovirus DFA	87271
➤	87475 Borrelia DNA	87480
➤	87485 Chlamydia DNA	87480
➤	87495 CMV direct probe	87480
➤	87528 Herpes direct probe	87480

Other Codes With No Data

▶ <i>CPT Procedure</i>	<i>Xwalk</i>
▶ 87537 HIV 2 direct probe	87480
▶ 87557 Mycobactria DNA quant	87592
▶ 87562 Mycobactria avium quant	87592
▶ 88130 Barr bodies	88148
▶ 88166 Pap, Bethesda	88164
▶ 88167 Pap, Bethesda, cell selection	88164
▶ 88245 Chromosome breakage	88248

Other Codes With No Data

➤ <i>CPT Procedure</i>	<i>Xwalk</i>
➤ 88741 Methemoglobin transcutaneous	88740
➤ 89320 Sperm, hamster	89331
➤ 0002M Liver disease, 10 assays	0003M
➤ 0004M Scoliosis DNA	81322
➤ 0006M Hepatic CA, risk classifier	81528
➤ 0007M Gastric neuroendocrine tumors	81528
➤ 0009M Fetal aneuploidy	81272
➤ G0147 Pap, auto	

Other Codes With No Data

➤ <i>CPT Procedure</i>	<i>Xwalk</i>
➤ P2028 Ceph Floc	82040
➤ P2029 Congo red	82040
➤ P2031 Hair analysis	82040
➤ P2033 Thymol turbidity	82040
➤ P2038 Mucoprotein	82040
➤ Q0113 Pinworm exam	Q0111



Anatomic Pathology

Medicare Physician Fee Schedule (MPFS)

- ▶ On July 21, 2017, CMS published the proposed changes to the 2018 Medicare Physician Fee Schedule (MPFS).
- ▶ CMS proposed changes include an overall 0.31% increase to payments under the MPFS.
 - ▶ This increase reflects the 0.5% positive adjustment mandated by the Medicare Access and CHIP Reauthorization Act (MACRA) which is reduced by 0.19% due to the misvalued code target recapture amount.
- ▶ CMS estimates the total impact in payments to pathology will decrease by 1% while independent laboratories could experience an overall 2% decrease in payments.

Medicare Physician Fee Schedule (MPFS)

- ▶ The proposed 2018 conversion factor (CF) is \$35.9903.
- ▶ Several codes were identified as misvalued in previous years and therefore, negative payment changes continue to be applied in 2018.





Therapeutic Apheresis Codes

<i>CPT</i>	<i>Description</i>	<i>%+</i>
36511	Therapeutic apheresis; for white blood cells	15%
36512	Therapeutic apheresis; for red blood cells	15%
36513	Therapeutic apheresis; for platelets	15%
36514	Therapeutic apheresis; for plasmapheresis	4%
36516	Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion	28%
36522	Photopheresis, extracorporeal	5%

Therapeutic Apheresis Code Deleted

- ▶ *CPT* *Description*
- ▶ 36515 Apheresis adsorp/reinfuse
 - ▶ Deleted in 2018





Pathology Consultation During Surgery Codes

- |  CPT | <i>Description</i> |
|---|--|
|  88333 | Pathology consultation during surgery; cytologic examination (eg, touch prep, squash prep), initial site |
|  PC | No change |
|  TC | -19.5 |

Pathology Consultation During Surgery Codes

- | ▶ CPT | Description |
|---------|--|
| ▶ 88334 | Pathology consultation during surgery; cytologic examination (eg, touch prep, squash prep), each additional site (List separately in addition to code for primary procedure) |
| ▶ PC | No change |
| ▶ TC | -16.1 |

Pathology Consultation for Second Opinion

 CPT	<i>Description</i>
 88323	<i>Consultation and report on referred material requiring preparation of slides</i>
 PC	-5%
 TC	-19%





Tumor Immunohistochemistry Codes

<i>CPT</i>	<i>Description</i>	<i>2017</i>	<i>2018</i>	<i>%</i>
88360 26	IHC manual	\$57.42	\$46.79	-19%
88360 TC	IHC manual	\$84.70	\$87.10	3%
88360	IHC manual	\$142.12	\$133.88	-6%
88361 26	IHC comput	\$61.01	\$49.67	-19%
88361 TC	IHC comput	\$95.82	\$91.78	-4%
88361	IHC comput	\$156.83	\$141.44	-10%

Tumor Immunohistochemistry Codes

<i>CPT</i>	<i>Description</i>	<i>2017</i>	<i>2018</i>	<i>%</i>
88342 26	IHC 1st stain	\$37.32	\$37.07	-1%
88342 TC	IHC 1st stain	\$71.06	\$71.26	0%
88342	IHC 1st stain	\$108.38	\$108.33	0%

Prostate Biopsy “G” Code

 <i>CPT</i>	<i>Description</i>
 G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method
 TC	-19%
 Global	-11.5%

Diagnostic Bone Marrow Services

All Changes

<i>CPT</i>	<i>Description</i>	<i>2017RV</i>	<i>2018RV</i>	<i>%</i>
38220	Diagnostic aspiration(s)	1.08	1.20	11%
	▶ Suspect description change; MUE 1			
38221	Diagnostic biopsy(ies)	1.37	1.28	-7%
	▶ Suspect description change; MUE 1			
382X3N	Diagnostic biopsy(ies) and aspiration(s)	NA	1.44	
	▶ New code			
G0364	Bone marrow aspiration	0.16	Deleted Code	

Flow Cytometry Codes

<i>CPT</i>	<i>Description</i>	<i>2017</i>	<i>2018</i>	<i>%</i>
88184	Flow 1 marker	\$61.73	\$61.18	-1%
88185	Flow add-on	\$37.68	\$30.59	-19%
88187	Flow, interp 2-8	\$59.22	\$48.23	-19%
88188	Flow, Interp 9-15	\$75.37	\$66.22	-12%
88189	Flow, interp >16 \$	92.59	\$88.54	-4%



Medicare Administrative Contractors & Coverage

Palmetto Wins 5 Year Contract

- ▶ The federal Centers for Medicare & Medicaid Services (CMS) has selected Palmetto GBA as the Medicare Administrative Contractor for Jurisdiction J, which includes the states of Alabama, Georgia and Tennessee.
 - ▶ Jurisdiction J represents seven percent of the national Part A/Part B claim-volume workload. These contracts are awarded following a competitive bidding process.
 - ▶ According to CMS, Jurisdiction J includes more than 2.5 million Medicare beneficiaries, more than 52,000 physicians and 400 hospitals that serve Medicare patients.

Palmetto Wins 5 Year Contract

- ▶ It will assume full responsibility for Part A claims by the end of January and Part B claims by the end of February 2018.
- ▶ *Welcome to MoIDx!!*



MoIDX Program - Next Generation Sequencing Coding and Billing Guidelines (M00127, V3)

► **Next Generation Sequencing (NGS)**

NGS allows identification of somatic and/or germline alterations in multiple genes simultaneously. This guideline focuses on Targeted and Comprehensive Genomic Profile testing for somatic variant detection using tumor tissue only-based panels. Panels involving germline variants, matched tumor-normal, or “liquid biopsies” (including circulating tumor cells (CTCs) or DNA (ctDNA), or cell-free DNA (cfDNA)) will be addressed separately, but should be billed using CPT 81479.

Next Generation Sequencing Coding and Billing Guidelines (M00127, V3)

- ▶ **Targeted (aka Hot Spot) Tumor Panels**
- ▶ Targeted NGS panels identify somatic alterations known to occur in certain areas (i.e., 'hotspots') in specific genes of interest. Generally, these NGS panels can detect single nucleotide variants (SNVs or point mutations) and small (typically ≤ 40 bp) insertions or deletions (indels), but not copy number alterations (CNAs) or structural variants (SVs), such as gene rearrangements, fusions, or translocations. These alterations typically represent genomic targets with corresponding targeted cancer therapies. Identification of a somatic alteration guides use of the corresponding targeted therapy.

Next Generation Sequencing Coding and Billing Guidelines (M00127, V3)

- ▶ To bill for targeted NGS services for somatic variant detection, review CPT codes 81445, 81450 and 81455. Select the appropriate CPT code based on the number of genes in your laboratory's NGS panel and the test indication for either solid organ or hematolymphoid neoplasms. The units of service (UOS) for an NGS panel is one (UOS=1).

Next Generation Sequencing Coding and Billing Guidelines (M00127, V3)

- Effective July 1, 2017, laboratories with 1 to 4 gene(s) on their targeted NGS panel should use CPT 81479 and one (1) UOS along with their test identifier (DEX Z-code) to represent this service on their claims. (Similarly, CPT 81479 should be used to bill for somatic variant detection performed by a targeted NGS panel on a “fluid” sample (e.g., KRAS in pancreatic cyst fluid). Reimbursement is based on the number of reported genes in these small NGS panels. *Tier 1 and/or Tier 2 individual biomarker CPT codes should not be used for a single gene or any combination of genes when testing is performed as part of a NGS or other multiplexing technology panel.*

Next Generation Sequencing Coding and Billing Guidelines (M00127, V3)

➤ **Comprehensive Genomic Profile (CGP) Testing**

CGP refers to NGS-based testing that has been optimized to identify all types of molecular alterations (i.e., SNVs, small and large indels, CNAs, and SVs) in cancer-related genes in a single test using complex and often proprietary bioinformatics. CGP may also include testing for MSI (microsatellite instability) and TMB (tumor mutational burden).

- Because CGP includes SNVs, small (≤ 40 bp) and large (> 40 bp) indels, CNAs, and SVs, CPT codes 81445, 81450, and 81455 do NOT describe a CGP service. Therefore, to report a CGP service, test providers should use CPT code 81479.

Biomarkers for Oncology LCD – Novitas Solutions

- ▶ An accompanying *article* was recently updated. The following instructions merit perusal:
- ▶ **Test Panel Definition:**
A predetermined set of medical tests composed of individual laboratory tests related by medical condition, specimen type, frequency ordered, methodology or types of components to aid in the diagnosis/treatment of diseases. The performance of multiple molecular tests regardless of whether the requisition lists the tests as a panel or individually, and completed on a single sample to be a Panel of tests and bill under a single CPT code to prevent stacking of codes.









Biomarkers for Oncology LCD Article – Novitas Solutions

- ▶ When multiple biomarkers are performed on one specimen and ordered in the context of a set panel of tests then this scenario should be billed as the specific panel if it has its own CPT code or as 81479 if it does not have a specific CPT code. Billing each code separately is incorrect billing and may result in the denial of the claim.










CCI & MUEs









New MUEs

 <i>Code</i>	<i>MUE</i>	<i>MAI</i>
 10021	4	3
 10022	4	3
 80500	1	3
 80502	1	3
 83020	2	3
 85060	1	3
 85097	2	3









New MUEs

 <i>Code</i>	<i>MUE</i>	<i>MAI</i>
 88104	5	3
 88106	5	3
 88108	6	3
 88112	6	3
 88120	2	3
 88121	2	3

New MUEs

 <i>Code</i>	<i>MUE</i>	<i>MAI</i>
 88172	5	3
 88173	5	3
 88177	6	3
 88312	9	3
 88313	8	3
 88314	6	3
 88319	11	3

New MUEs

 <i>Code</i>	<i>MUE</i>	<i>MAI</i>
 88341	9	1
 88342	3	3
 88344	1	1
 88380	1	1
 88381	1	1
 G0416	1	2
 G0452	6	3



Discussion



*Thank you for your
courtesy!*

Diana