

Coding & Billing Compliance 2020

LAB INSTITUTE

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Presented by

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Objectives

Discuss procedural and diagnosis coding changes for 2020

Describe proposed changes in government reimbursement

Discuss pertinent policies and issues affecting coverage

As time allows, delve into additional topics of interest or concern

Therapeutic Drug Monitoring

New Therapeutic Blood Monitoring Codes

CPT Description

80145 Adalimumab

- Typically prescribed for Crohn's disease or ulcerative colitis
- LC-MS-MS methodology
- Crosswalked to CPT 80155 (Caffeine)
 - Allow \$38.57 in 2019

New Therapeutic Blood Monitoring Codes

CPT Description

80187 Posaconazole

- Prescribed for immunocompromised patients to prevent certain fungal infections
- HPLC common methodology
- Crosswalked to CPT 80199 (tiagabine)
 - Allow \$27.11 in 2019

New Therapeutic Blood Monitoring Codes

CPT	Description
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#80230	Infliximab
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- Typically prescribed for Crohn's disease or ulcerative colitis
- LC-MS-MS methodology
- Crosswalked to CPT 80155 (Caffeine)
 - Allow \$38.57 in 2019

New Therapeutic Blood Monitoring Codes

CPT Description

#80235 Lacosamide

- Prescribed for patients with partial-onset seizures
- HPLC or IA typical methodology
- Crosswalked to CPT 80199 (tiagabine)
 - Allow \$27.11 in 2019

New Therapeutic Blood Monitoring Codes

CPT Description

#80280 Vedolizumab

- Typically prescribed for Crohn's disease or ulcerative colitis
- LC-MS-MS methodology
- Crosswalked to CPT 80155 (Caffeine)
 - Allow \$38.57 in 2019

New Therapeutic Blood Monitoring Codes

CPT	Description
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#80285	Voriconazole
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- Patients that may have a specific genetic mutation to the prescribed antifungal agent
- HPLC typical methodology
- Crosswalked to CPT 80199 (tiagabine)
 - Allow \$27.11 in 2019

Therapeutic Coding Caveats

- Distinguish therapeutic monitoring from presumptive and definitive testing
- Therapeutic testing is used to monitor patient response to a prescribed drug:
 - Track effect of dosage changes
 - Check for toxicity
 - Determine effectiveness of dose
 - Monitor drug interactions
 - Response to clinical changes
 - Evaluate patient compliance

Molecular Pathology

New Tier 1 Code

- CPT Description
- #81277 Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of heterozygosity variants for chromosomal abnormalities
- Similar description removed from CPT 81406 listing
 - “cytogenomic array analysis for neoplasia” removed from descriptor
 - \$283 in 2019 **CMS Crosswalk to CPT 81229 (\$1160 in 2019)**

New Tier 1 Codes

- CPT Description
- #81307 PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence
- #81308 known familial variant
- Gene removed from listing in CPT 81406
 - \$283 in 2019

New Tier 1 Code

- CPT Description
- #81309 PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)
- Gene removed from listing under CPT 81404
 - \$275 in 2019

Tier 1 Code Revision

- CPT Description
- 81350 UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, ~~irinotecan~~ **drug** metabolism, **hereditary unconjugated hyperbilirubinemia [Gilbert syndrome]**), gene analysis, common variants (eg, *28, *36, *37)
- \$234 in 2019

Tier 2 Listing Addition

- CPT Description
- 81404 UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, hereditary unconjugated hyperbilirubinemia [Crigler-Najjar syndrome]) full gene sequence
 - \$275 in2019

Tier 2 Listing Addition

- CPT Description
- 81407 APOB (apolipoprotein B)(eg, familial hypercholesterolemia type B) full gene sequence
- Common variants are listed under CPT 81401
 - 81407 = \$846 in 2019
 - 81401 = \$137 in 2019

Multianalyte Assays with Algorithmic Analyses (MAAAs) – New Code

- CPT Description
- #81522 Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
- EndoPredict from Myriad Genetics
 - Crosswalk to CPT 81518 (\$3873 in 2019)

Multianalyte Assays with Algorithmic Analyses (MAAAs) – New Code

- CPT Description
- 81542 Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as metastasis risk score
- Decipher Prostate from Decipher Biosciences
 - Gapfill

Multianalyte Assays with Algorithmic Analyses (MAAAs) – New Code

- CPT Description
- 81552 Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
- DecisionDx – UM test from Castle Biosciences
 - Was 0081U PLA
 - Crosswalk to CPT 81518 (\$3873 in 2019)

Deleted MAAA Code

- CPT Description
- 0009M Fetal aneuploidy (trisomy 21, and 18) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy).
- VisibiliT test from Sequenom

Proprietary Laboratory Analysis (PLA)

PLA Codes

- 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]).
- When a PLA code is available to report a given proprietary laboratory service, that PLA code takes precedence.

PLA Codes

- PLA test codes are released on a quarterly basis and published on the CPT public website at www.ama-assn.org/practice-management/cpt-pla-codes
- The initial set of codes became effective on January 1, 2018
- New PLA codes become effective in the quarter following their approval and publication
- The PLA subsection includes ADLTs and CDLTs

PLA Codes

- The standards for inclusion in the PLA section are:
 - The test must be commercially available in the United States for use on human specimens and
 - The clinical laboratory or manufacturer that offers the test must request the code.
- All codes that are included in this section are also included in Appendix O, with the procedure's proprietary name.
- In order to report a PLA code, the analysis performed must fulfill the code descriptor and must be the test represented by the proprietary name listed in Appendix O.

PLA Codes

- In some instances, the descriptor language of PLA codes may be identical and the code may only be differentiated by the listed proprietary name in Appendix O.
- When more than one PLA has an identical descriptor, the codes will be denoted by the symbol “)-(.”
- Any PLA coded test(s) that satisfies Category I criteria and has been accepted by the CPT Editorial Panel will be designated by the addition of the symbol “↑↓” to the existing PLA code and will remain in the PLA section of the code set.

PLA Codes

- PLA codes 0001U through 0017U published in 2018 CPT
- PLA 0018U through 0061U added in 2019 CPT publication
- PLA 0062U through 0138U added in 2020 CPT publication
 - See CPT or AMA website
 - Carrier priced until discussed at annual clinical laboratory public meeting in July

Deleted PLA Codes in 2019 CPT

- *CPT* *Description*
- *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

Deleted PLA Codes in 2019 CPT

- *CPT* *Description*
- 0028U CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, copy number variants, common variants with reflex to targeted sequence analysis
 - CYP2D6 Genotype Cascade; Mayo Clinic (81226?)
- 0057U Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank (RNA Sequencing by NGS)
 - OmniSeq, Inc.; Life Technologies Corporation) (81445?)

Deleted PLA Codes in 2019 CPT

- *CPT* *Description*
- 0081U Converted to new code 81552
- 0104U Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only]) (81432?)
- CancerNext, Ambry Genetics; Ambry Genetics

Microbiology

New CPT Code

- CPT Description
- 87563 Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma genitalium, amplified probe technique
 - Crosswalk to CPT 87491 (\$38.99 in 2019)

Fine Needle Aspiration

FNA 2020

- CPT Descriptions
- 10021 Fine needle aspiration **biopsy, without imaging guidance;** ~~without imaging guidance~~ first lesion
 - \$101.05 in 2020 (up 1% CAP)

~~10022~~ ~~with imaging guidance~~

- (10022 has been deleted. To report, see 10005, 10006, 10007, 10008, 10009, 10010, 10011, 10012)
- Codes 10004 – 10012 have same descriptors but add-on codes indicated (+)

FNA 2020

- CPT Descriptions
- #+10004 each additional lesion (List separately in addition to code for primary procedure)
 - \$52.69 in 2020 (Down 2% CAP)
- (Do not report 10004, 10021 in conjunction with 10005, 10006, 10007, 10008, 10009, 10010, 10011, 10012 for the same lesion)
- (For evaluation of fine needle aspiration, see 88172, 88173, 88177)

FNA 2020

CPT	Descriptions
#10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion \$133.53 in 2020
#+10006	each additional lesion (List separately in addition to code for primary procedure) ◦ \$61.35 in 2020
#10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion \$303.48 in 2020
#+10008	each additional lesion (List separately in addition to code for primary procedure) ◦ \$172.44 in 2020

FNA 2020

CPT	Description
#10009	Fine needle aspiration biopsy, including CT guidance; first lesion \$479.52 in 2020
#+10010	each additional lesion (List separately in addition to code for primary procedure) \$288.72 in 2020
#10011	Fine needle aspiration biopsy, including MR guidance; first lesion Carrier discretion
#+10012	each additional lesion (List separately in addition to code for primary procedure) Carrier discretion

FNA 2020

- (For percutaneous needle biopsy other than fine needle aspiration, see 19081-19086 for breast, 20206 for muscle, 32400 for pleura, 32405 for lung or mediastinum, 42400 for salivary gland, 47000 for liver, 48102 for pancreas, 49180 for abdominal or retroperitoneal mass, 50200 for kidney, 54500 for testis, 54800 for epididymis, 60100 for thyroid, 62267 for nucleus pulposus, intervertebral disc, or paravertebral tissue, 62269 for spinal cord)
- (For percutaneous image-guided fluid collection drainage by catheter of soft tissue [eg, extremity, abdominal wall, neck], use 10030)

Diagnosis Codes

Sampling of new ICD-10 Codes

- | ICD | Description |
|----------|--|
| ◦ Q79.60 | Ehlers-Danlos syndrome, unspecified |
| ◦ Q79.61 | Classical Ehlers-Danlos syndrome |
| ◦ Q79.62 | Hypermobile Ehlers-Danlos syndrome |
| ◦ Q79.63 | Vascular Ehlers-Danlos syndrome |
| ◦ Q79.69 | Other Ehlers-Danlos syndromes |
| ◦ D75.A | Glucose-6-phosphate dehydrogenase (G6PD) deficiency without anemia) to report the condition. |
| ◦ N63.15 | Unspecified lump in the right breast, overlapping quadrants |
| ◦ N63.25 | Unspecified lump in the left breast, overlapping quadrants |

Sampling of new ICD-10 Codes

- ICD Description
- D81.30 Adenosine deaminase deficiency, unspecified
- D81.31 Severe combined immunodeficiency due to adenosine deaminase deficiency
- D81.32 Adenosine deaminase 2 deficiency
- D81.39 Other adenosine deaminase deficiency
- R82.81 Pyuria
- R82.89 Other abnormal findings on cytological and histological examination of urine
- R11.15 Cyclical vomiting syndrome unrelated to migraine

Sampling of new ICD-10 Codes

ICD	Description
Z86.15	Personal history of latent tuberculosis infection
Z11.7	Encounter for testing for latent tuberculosis infection
Z22.7	Latent tuberculosis
Z86.002	Personal history of in-situ neoplasm of other and unspecified genital organs

Protecting Access to Medicare Act (PAMA)

Definition of “Applicable Laboratory”

- A laboratory, (as defined in CMS’s CLIA regulations), using its National Provider Identifier (NPI), is considered an applicable laboratory if more than 50 percent of its total Medicare revenues are received from payments under the CLFS and physician fee schedule (PFS).
- Additionally, an applicable laboratory would also have to receive at least \$12,500 in Medicare revenues received for CLFS services during a data collection period to be an applicable laboratory.
 - The \$12,500 will not apply to certain laboratories with respect to the ADLTs they offer and furnish.

PAMA Questionable Analysis

Estimate:

- 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

PAMA & ACLA

The judge with the U.S. District Court for Washington, DC dismissed ACLA's lawsuit that claimed the CLFS changes under PAMA were incorrectly calculated

- September 21, 2018 decision
- Section 216 of the PAMA statute prohibits administrative or judicial review regarding the setting of payment amounts
- The court does not have “subject matter jurisdiction”
- CMS's determination of payment rates cannot be challenged
- Additional 10% cuts at issue as well as original 2018 pricing

Final Rule – MPFS

November 1, 2018

CMS announced that it was including Medicare Advantage Program services in the definition of “applicable Laboratory” under PAMA

- “..we believe that modifying our definition of applicable laboratory so that we may receive applicable information from more laboratories that furnish tests to a significant Medicare Part C population, which are less likely to qualify for applicable laboratory status under the current policy, outweighs the additional reporting burden placed on these laboratories”
- “..directly supports our goal of collecting as much applicable information as possible from the broadest representation of the national laboratory market on which to base CLFS payment amounts”

Final Rule – MPFS

CMS announced that it was including hospital outreach laboratories in the definition of “applicable Laboratory” under PAMA

- “..we are finalizing the revision of the definition of applicable laboratory at §414.502 to include a hospital laboratory that bills Medicare on the Form CMS1450 14x bill type and its electronic equivalent.”

PAMA & ACLA

- ACLA appealed the ruling and argued that “Congress precluded judicial review of only the establishment of payment amounts. It did not bar review of the Secretary’s final regulations establishing the parameters for collecting confidential information from laboratories.”
- Appeals court upheld ACLA’s logic
 - Distinguish between data collection and rate estimate provisions
- Case goes back to District of Columbia
- MEANWHILE.....

THE LABORATORY ACCESS FOR BENEFICIARIES (LAB) ACT - H.R. 3584

On June 28, 2019, [The Laboratory Access for Beneficiaries \(LAB\) Act](#), was introduced by The bill would delay the next round of PAMA data reporting by one year to ensure that all applicable laboratories that are required to report private payor data have the necessary time to do so.

The bill also calls for the National Academy of Medicine (NAM) to provide recommendations to Congress on less burdensome data collection methods and representative reimbursement rate calculations that result in the reliable, sustainable, market-based system originally intended by Congress.

- Congress has yet to post the bill

Physician Reimbursement

Medicare Physician Fee Schedule

CAP stresses that CMS is intending to shift monetary support to primary care providers

- The overall impact on pathology is estimated a negative 8%
- Includes Independent Laboratories

Using Pap test as the extreme example, the RVU would drop from .42 to .26

- 38% decrease

CF was \$36.04 in 2019 and raising to \$36.09 for 2020

CAP has an extensive analysis on its website

Medicare Physician Fee Schedule

- The [CY 2020 Medicare Physician Fee Schedule Final Rule](#) was placed on display at the Federal Register on November 1, 2019
- This final rule updates payment policies, payment rates, and other provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after Jan. 1, 2020

NCCI Manual Content

NCCI Molecular Pathology - 2019

“A Tier 1 or Tier 2 molecular pathology procedure CPT code shall not be reported with a genomic sequencing procedure, molecular multianalyte assay, multianalyte assay with algorithmic analysis, or proprietary laboratory analysis CPT code where the CPT code descriptor includes testing for the analyte described by the Tier 1 or Tier 2 molecular pathology code.”

- See 2 additional comments re: repeat gene testing and bundling

Coverage Issues

Technical Assessment requirement for NGS Cancer Tests - MoDx

MoDx has released **two new draft LCDs** regarding next generation sequencing (NGS) testing for solid tumor and myeloid malignancies. Among the coverage requirements for tests within the scope of these LCDs is a requirement that all of these tests undergo technical assessment by the MoDx program.

This requirement will apply not only to new tests seeking coverage but also to tests that are currently covered in order to maintain coverage.

While MoDx has always required technical information on tests before processing claims for tests, **there are now new technical assessment documents requiring a level of information that has only previously been required for coverage of comprehensive genomic profiles.**

Technical Assessment requirement for NGS Cancer Tests - MoIDx

As such, any tests currently covered or being reimbursed that are within the scope of these **LCDs that are not:**

- FDA approved, or
- Already covered as a comprehensive genomic profile, or
- Covered with their own LCD or article

will require submission of new technical assessment information and verification by the MoIDx program that the test has been adequately validated so as to be **reasonable and necessary to maintain coverage**. Please see the full text of the LCDs and documents linked below for further information.

- Next-Generation Sequencing for Solid Tumors ([DL38045](#))
- Next-Generation Sequencing for Myeloid Malignancies and Suspected Myeloid Malignancies ([DL38047](#))

Medicare NCD for NGS (3/16/18)

- In general, the NCD provides national coverage for diagnostic laboratory tests using NGS that have FDA approval or clearance as a:
 - Companion *in vitro* diagnostic for patients with recurrent, relapsed, refractory, metastatic, or advanced cancers,
 - An FDA approved or cleared indication for use in that patient's cancer,
 - And results provided to the treating physician for management of the patient using a report template to specify treatment options.

Medicare NCD for NGS – Extension?

CMS initiated this national coverage determination (NCD) to reconsider the **evidence available for NGS tests of germline (inherited) mutations to identify those with inherited cancer who may benefit from targeted treatments based on results of the test.** All other tests are beyond the scope of this reconsideration.

The scope of this review is limited to next generation sequencing tests of **germline mutations to identify patients with inherited cancer at any stage.** NGS testing for all other indications, including early stage somatic cancer, is outside the scope of this NCD.

Proposed NGS Decision Memo

- Does NGS as a diagnostic test, either to detect **germline mutations or identify inherited cancers, improve health outcomes** for Medicare beneficiaries with inherited cancers?
- The Centers for Medicare & Medicaid Services (CMS) proposes that the evidence is sufficient to **expand** coverage of Next Generation Sequencing (NGS) as a diagnostic laboratory test when performed in a CLIA-certified laboratory, when ordered by a treating physician and when **all of the following requirements are met:**

Proposed NGS Decision Memo

The patient has:

- Ovarian or breast cancer;
- Clinical indications for germline (inherited) testing,
- Risk factors for germline (inherited) breast or ovarian cancer; and
- Not been previously tested using NGS

The diagnostic laboratory test using NGS must have all of the following:

- Food and Drug Administration (FDA) approval or clearance;
- An FDA approved or cleared indication for use in that patient's cancer; and
- Results provided to the treating physician for management of the patient using a report template to specify treatment options.

Proposed NGS Decision Memo

- Medicare Administrative Contractors (MACs) may determine coverage of **other** Next Generation Sequencing (NGS) as a diagnostic laboratory test when performed in a **CLIA**-certified laboratory, when **ordered by a treating** physician, when **results** are provided to the treating physician for **management of the patient and when all the following conditions are met:**
- The patient has:
 - a **cancer diagnosis other than breast or ovarian cancer,**
 - clinical indications for **germline** (inherited) testing,
 - **risk factors for germline** (inherited) cancer other than inherited breast or ovarian cancer, and
 - **not been previously tested using NGS**

United Healthcare Policy for Molecular Pathology

- Effective November 1, 2019
- Affects claims with Tier 1 and/or Tier 2 codes
- The most specific code available must be reported
 - When multiple gene procedures (considered a panel) are provided, a proprietary laboratory analysis (PLA) code would take precedence.
 - If no approved PLA code is applicable, then a Tier 1 or Tier 2 Molecular Pathology code, such as a genomic sequencing procedure (GSP) code would be applied.
 - If a Tier 1 code exists for the procedure, it must be submitted with a Tier 1 code, a Tier 2 code is not accepted.
 - Only if no other code describes the services can an unlisted code, such as 81479 be used.

United Healthcare Policy for Molecular Pathology

- UHC will require providers to indicate the specific gene when submitting a Tier 2 Molecular Pathology code
- An unlisted code, such as 81479 can only be used once per patient, per specimen, and date of service.
 - If billed on the same date of service as a PLA or GSP, the PLA or GSP will take precedence, as only one is allowed to be billed per day
- When billing with an unlisted code, such as 81479, the test must be registered with the [National Institute of Health \(NIH\) Genetic Testing Registry](#).

United Healthcare Policy for Molecular Pathology

- In addition:
 - The condition/disorder tested data must be placed in the test name or long test description field
 - The specimen type must be included in the long test description field
 - The details of the CPT codes must be included in the long test description field
- The AMA claim designation code and the GTR unique test ID should be reported in Loop 2400 or SV101-7 field for electronic claims and in Box 19 for paper claims

Discussion

Thank you for your courtesy!

Diana