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Meet the Presenter…

On the topic:
Billing and Coding for Path & Lab Services

Maxine Collins
MBA, CPA, CMC, CMIS, CMOM
Faculty
Practice Management Institute
Billing and Coding for Pathology & Laboratory Services

Presented by: Maxine I. Collins
MBA, CPA, CMC, CMOM, CMIS
Faculty/Consultant
Practice Management Institute
Executive Director of Compliance, Auditing, and Education
CoreMDPartners, LLC.

Medicare Clinical Laboratory and Pathology Services

• Before Medicare pays for any test or diagnostic service, 2 criteria must be met:
  1. Service must be a covered service by Medicare,
  2. Service must be medically necessary or indicated
• Medicare tests must be billed on an assigned basis:
  – Provider must accept the Medicare reimbursement as payment in full for covered laboratory test (This applies regardless of whether the physician is a participating or non-participating provider).
  – Medicare patients may not be billed for any additional amounts for covered test.
  – Direct billing is required for all Medicare-reimbursed laboratory tests – must be billed directly to Medicare by the laboratory or physician who performed the tests. If an outside lab performs a test on a referral from a physician, only the reference lab may legally bill Medicare for the service.

(CodeMap, n.d.)
Hospitals, Reference Labs. and Medicare

- Hospitals and reference labs that send specimens to other labs may bill Medicare for tests performed by other labs if the referring lab meets any one of the following 3 exceptions:
  - Referring lab is located in or is part of a rural hospital;
  - Referring lab is wholly owned by reference lab or the referring lab wholly owns the reference lab, or both referring lab and reference lab are wholly owned by a third entity; or
  - No more than 30% of clinical diagnostic tests for which a lab receives requests annually are performed by another lab other than an ownership related lab. For purpose of the 30% exception, each CPT code billed counts as one test. Example- when CPT code 80054 is billed, it is counted as one test although 12 test are performed.

(Medicare Claims Processing Manual, 2015)

Services in the Path and Lab Section of CPT© Not Included In Medicare Clinical Lab Fee Schedule

- The following services are paid under the PFS and are subject to deductible and co-pay:
  - Clinical pathology consultations
  - Bone marrow smears and biopsy
  - Blood bank physician services
  - Skin tests
  - Anatomical and surgical pathology services
  - Duodenal and gastric intubation
  - Sputum and sweat collection

(Medicare Claims Processing Manual, 2015)
Appendix – Analysis of Some Changes In Path & Lab 2016 CPT

Numerous changes that include:

- **Molecular Tier 1 & Tier 2 subsections**
  - Have substantial subsections
  - A number of additions, revisions

- **New Obstetric panel – code 80081 – OB panel (includes HIV testing)**
  - Includes HIV testing to the Organ or Disease-Oriented Panels Subsection
  - To address reporting requirements from various organizations.

- **Genomic Sequencing Procedures (GSPs – DNA or RNA sequence analysis methods) and Other Multianalyte Assays:**
  - 7 Codes established (81412, 81432, 81433, 81434, 81437, 81438, & 81442); and
  - 5 Codes revised (81435, 81436, 81445, 81450, & 81455) in the Genomic Sequential Procedures;
  - Other Molecular Multianalyte Assays Subsection to include new guidelines explaining correct reporting of new assay codes.

Changes – Continued

- **Chemistry subsection:**
  - (82000 has been deleted); (82003 has been deleted. For acetaminophen, see 80329, 80330, 80331).
  - Revised guidelines and code deletions to simplify the reporting of chromatography procedures which is accomplished by revised codes 82542 (Column chromatography) & 83789. (Mass spectrometry and tandem mass spectrometry)

- **Microbiology code – 87301 (Infectious agent antigen detection by immunoassay technique):**
  - Revisions that affect numerous series of subset codes within that section.
  - Changes allow expansion of these codes to include reporting of infectious agent antigen detection by any immunoassay technique.

- **Surgical Pathology:**
  - Subsection revisions made to redefine codes for immunofluorescence studies. (Revised code 88346 and new add-on code 88350)
Exciting New Procedures – Analysis of CPT® Code 81425 – Genomic Sequencing Procedures and Other Molecular Multianalyte Assays

- 81525 – Oncology (colon), mRNA gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrent score.
  - Multianalyte Assays with Algorithmic Analysis (MAAAs):
    - Procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays (e.g., proteins, polypeptides, lipids, carbohydrates).
    - Algorithmic analysis using results of these assays as well as other patient information (if used) is then performed and typically reported as a numeric score(s) or as a probability.
    - MAAAs are typically unique to a single clinical laboratory or manufacturer.
    - Results of individual component procedures(s) that are inputs to the MAAAs may be provided on the associated lab report; however, these assays are not separately reported using additional codes.

(CLFS 2016 CMS Proposed Determinations)

- Current coding for testing for drugs of abuse:
  - relies on a structure of “screening” (presumptive testing) followed by
  - “confirmation” – to confirm results of screening and quantitative or “definitive” testing that identifies specific drug and quantity is patient.
  - CMS decided not to pay 2015 CPT codes for drugs of abuse testing because of their concern about the potential for overpayment when billing for each individual drug test rather than a single code that pays the same amount regardless of the # of drugs tested.
    - Pricing was delayed for CMS to study issue.
    - Finally, 2014 status quo for 2015 was withheld by the creation of a “G” code to replace 2014 CPT codes that were deleted for 2015.
    - For 2015, providers used the “G” codes in the same manner in which they used the corresponding CPT codes exactly as used in 2014, regardless of 2015 instructions or code descriptor changes.
    - July, 2015 – CMS proposed to delete all current drug testing “G” codes, continue to not recognize the new AMA CPT codes, and create a single “G” code for presumptive testing and a single “G” code for definitive testing.
CMS Releases 2016 HCPCS Codes 12/02/2015 for Drug Testing

• Too late for publishing in Manuals.
• Effective 01/01/2016:
• New Codes for Presumptive Testing (Screening):
  – G0477 Drug test presumptive-optical only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service: Natl limit - $14.86; Median - $20.08
  – G0478 Drug test, presumptive- instrument-assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service: Natl limit - $19.81; Median - $26.78
  – G0479 Drug test, presumptive – by instrumented chemistry analyzers, utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry, includes sample validation when performed, per date of services: Natl limit - $79.94; Median - $108.03  
  (Ericson, 2015)

New Codes for 2016 for Definitive Drug Testing For CMS

• New codes for definitive drug testing (Diagnostic):
  – G0480 Drug test, definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug classes, including metabolite(s), if performed. Natl limit - $79.94; Median $108.03
  – G0481 Drug test, definitive, """, 8-14 classes: Natl Limit - $122.99; Median = $166.20
  – G0482 Drug test, definitive, """, 15-21 classes: Natl Limit - $166.03; Median - $224.37
  – G0483 Drug test, definitive, """, 22+ classes: Natl Limit - $215.23; Median - $290.85
• Note: 60% of NLA is set at 74$ of 2016 Median; 62% NLA is calculated by (60% of NLA/0.60) * 0.62). If floor is applicable, then NLA is appropriately adjusted.  
  (CMS, n.d.)
Deleted/Revised HCPCS Codes 01/01/16

- **Deleted:**
  - G0298 Replaced by G0475;
  - G6030-G6032; G0434-G6058;
  - G9668

- **Revised:**
  - G0472 Add pricing indicator;
  - G8925 Change Short and Long Description – Spirometry test results;
  - G9226 Remove ? In Long Description – Foot exam performed
  - G9448 Remove ? In Long Description – Patients who were born in the years 1945-1965;
  - G9574 Remove the period in Long Description – Remission at 6 months not demonstrated by a six month score of less than 5....
  - G9676 Remove ? In Long Description – Patients aged 40 to 75 years at beginning of measurement period w/Type1 or Type2 DM.......
Market-based System – Effective: 01/01/2017

PROPOSED CHANGES IN CLINICAL LAB FEE SCHEDULE FOR CMS

CMS and Changes In the Clinical Laboratory Fee Schedule

• Medicare pays for clinical diagnostic laboratory tests (CDLT) under the CLFS. The **CLFS provides payment for approximately 1,300 CDLTs and Medicare pays approximately $8 billion per year for these tests.**
  – CLFS was first adopted in 1984.
  – Payment rates were based on charges to the Medicare program.
  – CLFS rates have only been updated since that time to establish payment for new tests or to make statutory, across-the-board updates to the CLFS.
  – Payment for a new test code on the CLFS established after 1984 is based on either crosswalking, where an existing test(s) with similar methodology and resources is used as a basis for the payment amount or gapfilling, where a test with no similar methodology is tasked to the Medicare Administrative Contractors to develop a payment amount.

("Medicare Clinical Diagnostic Laboratory," 2015)
Proposed CMS Market-based Payment System – CLFS Payments On or After 01/01/2017

• In general, the payment amount for a test on the CLFS furnished on or after January 1, 2017:
  - Will be equal to the weighted median of private payor rates determined for the test based on:
    • Data collected by applicable laboratories during a specified data collection period and
    • Reported to CMS during a specified data reporting period.
  - In addition, a subset of tests on the CLFS, advanced diagnostic laboratory tests (ADLTs), will have different data collection, reporting, and payment policies associated with them.”
  • HCPCS Level II “G” codes will be utilized for Medicare payments.

(“Medicare Clinical Diagnostic Laboratory,” 2015)

Why the Changes?

• CLFS has grown from approximately 400 tests to over 1,300 test
• Some test methods have become outdated
• Some test may no longer be priced appropriately
• Some test have become faster and cheaper to perform, with little need for manual interaction by laboratory technicians
• More expensive and complex tests have been developed that bear little resemblance to the simpler tests that were performed at the inception of the CLFS
• CMS states they must also consider the various types of laboratories that bill Medicare under the Lab Fee Schedule
  - Medicare-enrolled labs include a mix of national chains that furnish a large menu of tests, and small regional operations that may concentrate on a specific population, such as nursing home residents, or that have a small menu of test.
  - Physician offices also perform certain tests that are paid under the CLFS

(“CMS Proposes New Medicare,” 2015)
Excerpt from the Federal Register, 10/01/2015  
Department Of Health And Human Services  

• Centers for Medicare & Medicaid (CMS-1621-P) – Proposed Rule  
• Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System  
  – Summary  
    • This proposed rule would significantly revise the Medicare payment system for clinical diagnostic laboratory tests and would implement other changes required by section 216 of the Protecting Access to Medicare Act of 2014.  
  – Further Information Contact  
    • Marie Casey (410) 786-7861 or Karen Reinhardt (410) 786-0189 for issues related to the local coverage determination process for clinical diagnostic laboratory tests;  
    • Valerie Miller (410) 786-4535 or Sarah Harding (410) 786-4001 for all other issues.  

(Federal Register, 2015)  

Medicare Update – 2016 – PAMA Regulations on Future Clinical Fee Schedule  

• PAMA Regulations:  
  – The Clinical Laboratory Fee Schedule (CLFS) proposed rule:  
    • Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System (CMS-1621-P)  
      – Went on display in the Federal Register on September 25, 2015.  
      – Under the proposed rule, laboratories and physician offices are required to report private payor rate and volume data if they have more than $50,000 in Medicare revenues from laboratory services and they receive more than 50% of their Medicare revenues from laboratory and physician services.  
      – Data to be collected on private payor data from 07/01/2015 through 12/31/2015, and report it to CMS by 03/31/2016.  
      – CMS will post the new Medicare CLFS rates (based on weighted median private payor rates) in November, 2016 that will be effective for 01/01/2017.  

(*PAMA Regulations,* 2015)
Applicable Labs

- A laboratory that receives more than 50% of its Medicare revenues from services paid under the CLFS and the Physician Fee Schedule (PPS).
- Labs identifies at the Taxpayer Identification Number (TIN) level rather than at the NPI level.

("Medicare Clinical Diagnostic Laboratory," 2015)

Required Reporting By Applicable Labs

For each test on the CLFS it performs:

1. Payment rate by each private payor for each test during data collection period
   - (Private payor rate – price for a test prior to application of any patient deductible and coinsurance amounts)
2. Volume of such tests for each such payor.
   - Must report to CMS for period of 07/01/2015 – 12/31/2015 for first reporting period. All subsequent will be on a calendar year basis.
   - Reporting due by March 31 of the year following the data collection period.
   - Reporting for new Advanced Diagnostic Laboratory Test (ADLTS) must be reported by end of the 2nd quarter of the new ADLT initial period.
   - Penalties for not reporting? Civil Monetary Penalties to be applied if Secretary determines that an applicable lab failed to report, or has made a misrepresentation or omission in reporting in an amount up to $ 10,000 per day for each failure to report or each such misrepresentation or omission.

("Medicare Clinical Diagnostic Laboratory," 2015)
PAMA Regulations

• Tests that meet the criteria for being considered - new advanced tests (ADLT) – will be paid at actual list charge for a minimum of three quarters.
  - Once initial period is over, payment for new advanced tests would be based on the weighted median private payor rate reported by the single laboratory that performs the new ADLT.
  - Advanced tests are those that are furnished by only one laboratory that include a unique algorithm and, at a minimum, are analysis of RNA or DNA – or are cleared or approved by the U.S. Food and Drug Administration (FDA).
  - CMS will solicit comments until November, 24, 2015. Instructions on how to submit comments can be found in the proposed rule.
  - The proposed rule was published on 10/01/2015 and can be downloaded from "Downloads" section on the CMS website.

("PAMA Regulations," 2015)

How Will Payment Changes Be Implemented by CMS?

• Phase-in of payment reductions:
  - For years 2017 through 2022, payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts:
    - 1. 2017 – 10% of the national limitation amount (NLA) for the test in 2016
    - 2. 2018 - 10% of payment rate established in 2017
    - 3. 2019 - 10% of payment rate in 2018
    - 4. 2020 - 15% of payment rate in 2019
    - 5. 2021 - 15% of payment rate in 2020
    - 6. 2022 - 15% of payment rate in 2021
Estimates From CMS – 2016 PFS To Have Positive Impact On Pathology, Independent Labs

2016 Physician Fee Schedule Final Rule:

• First physician fee schedule since the SGR repeal

• CMS predicts positive changes for:
  • Pathology Services – 8%:
    • Work relative value units (RVU) changes - + 4%
    • Practice Expense RVU changes - + 4%
  • Independent Laboratories – 9%:
    • Work relative value units (RVU) changes - + 1%
    • Practice Expense RVU changes - + 7%

  (CMS indicates the 1% and the 7% don’t precisely equal the predicted 9% due to rounding).

2016 RVUs for Pathology Services

• CMS – Effect of block numbers and batch size on pathology services – proposed standard times for certain clinical labor activities:
  – CMS believes certain activities require same time commitment regardless of:
    • service performed in connection with; and
    • regardless of number of blocks or batch sizes involved.
  – Did not find information that “convinced the agency that some tasks take “significantly more or less time depending on individual service for which performed”*
  – Clinical labor tasks with same work description are comparable across different pathology procedures.
  – Discussed in connection with prostate biopsy reimbursement under G0416 – CMS accepted the Relative Update Committee’s (RUC’s) recommendations for practice expenses but is soliciting evidence regarding “typical batch and block size used in furnishing this service because they received comments that these can be “significantly lower” than accounted for in the RUC recommendations.
Labor Cost Inputs for Certain Laboratory Services

- Several comments received by the public stated that they believed CMS’s estimate of per-minute labor cost inputs are too low for laboratory technicians, cytotechnologists and histotechnologists.
  - Some saying that complexity of many lab services demands highly-skilled, highly-trained, certified, and experience personnel who typically have to be paid higher wages that the current rates reflected by CMS.
  - CMS, however, states that the clinical labor costs per minute are based on data from Bureau of Labor Statistics and that it “is important to update that information uniformly among clinical labor types and will consider updating the cost per minute in directly PE database in future rulemaking”

OIG

In 2016, the OIG plans to conduct an annual analysis of Medicare clinical diagnostic laboratory tests:
- To examine expenditures; and
- The new payment system
Let’s take a look at the regulations – who is responsible for what?

FROM CMS MEDICARE MANUAL – SECTION 10

Medicare Provider Manual
Section 10 – Background

- Diagnostic X-ray, laboratory and other diagnostic tests, including materials and the services of technicians, are covered under the Medicare program.
- Some lab procedures require FDA approval before coverage is provided.
- A diagnostic lab test is considered a laboratory service for billing purposes, regardless of whether it is performed in:
  - A physician’s office, by an independent laboratory,
  - By a hospital laboratory for its outpatients or nonpatients,
  - In a rural health clinic, or
  - In an HMP or Health Care Prepayment Plan (HCPP) for a patient who is not a member.

(Medicare Benefit Policy Manual, 2014)
Definitions from the Medicare Manual Section 10.1

- **Independent Laboratory** – a lab that is independent both of an attending or consulting physician’s office and of a hospital that meets at least the requirements to qualify as an emergency hospital as defined in P1861(e) of the Social Security Act (the Act) (See the Medicare Benefits Policy Manual, Chapter 15 for detailed discussion.)

- **Physician Office Laboratory** – a lab maintained by a physician or group of physicians for performing diagnostic tests in connection with the physician practice

- **Referring Laboratory** – a Medicare-enrolled lab that receives a specimen to be tested and that refers the specimen to another laboratory for performance of the laboratory test.

- **Reference Laboratory** – a Medicare-enrolled lab that receives a specimen from another, referring laboratory for testing and that actually performs the test.

( Medicare Claims Processing Manual, 2015)

Definitions – Continued

- **CLIA** – Clinical Laboratory Improvement Act and CMS implementing regulations and processes.

- **Certification** – a laboratory that has met the standards specified in CLIA.

- **Draw Station** – a place where a specimen is collected but no Medicare-covered clinical laboratory testing is performed on the drawn specimen.

(Medicare Claims Processing Manual, 2015)
### Section 10.2 – General Explanation of Payment

- Outpatient laboratory services can be paid in different ways:
  - Physician Fee Schedule;
  - 101% if reasonable cost (critical access hospitals (CHA) only);
  - Laboratory Fee Schedule’
  - Outpatient Prospective Payment System (OPPS) except for most hospitals in the State of Maryland that are subject to a waiver, or
  - Reasonable charge.
- Annually, CMS distributes a list of codes and indicates the payment method.

*(Medicare Claims Processing Manual, 2015)*

### Section 30.1 – Mandatory Assignment for Laboratory Tests

- Unless a laboratory, physician, or medical group accepts assignment, the carriers makes no Part B payment for lab tests paid on the laboratory fee schedule.
  - Labs, physicians, or medical groups that have entered into a participating agreement must accept assignment.
  - *Sanctions of double the violation charges, civil monetary penalties (up to $2,000 per violation), and/or exclusion from the program for a period of up to five years* may be imposed on those, with the exception of rural health clinic labs, that knowingly, willfully, and repeatedly bill patients on an unassigned bases.

*(Medicare Claims Processing Manual, 2015)*
Section 30.1 – Mandatory Assignment for Laboratory Tests (cont.)

• Unless a laboratory, physician, or medical group accepts assignment, the carriers make no Part B payment for lab tests paid on the laboratory fee schedule.
  – Rural Health Clinics (RHCs) must furnish the following lab services to be approved as an RHC. However, these and other lab services that may be furnished are not included in the encounter rate and must be billed separately:
    • Chemical examinations of urine by stick or tablet method or both; Hemoglobin or hematocrit; Blood sugar; Examination of stool specimens for occult blood; Pregnancy test; and Primary culturing for transmittal to a certified laboratory (No CPT code available).
  – Effective 01/01/ freestanding RHCs/Federally Qualified Health Centers (FQHCs) bill all laboratory services to the carrier, and provider based RHCs/FQHCs bill all lab tests to the FI under the host provider’s bill type. In either case payment is made under the fee schedule. HCPCS codes are required for laboratory services.

(Medicare Claims Processing Manual, 2015)

Section 30.2 – Deductible and Coinsurance

• Neither the annual cash deductible nor the 20% coinsurance apply to:
  – Clinical laboratory tests performed by a physician, laboratory, or other entity paid on an assigned basis;
  – Specimen collection fees; or
  – Travel allowance related to laboratory tests (eg, collecting specimen)

(Medicare Claims Processing Manual, 2015)
Section 40.8 – Date Of Service (DOS) for Clinical Lab and Path Specimens

• The DOS for either a clinical laboratory or the technical component of physician pathology service is as follows:
  – **General rule**: DOS of test/service must be date the specimen was collected.
  – **Variation**: If a specimen is collected over a period that spans two calendar days, then the DOS must be the date the collection ended.

(Medicare Claims Processing Manual, 2015)

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Section 40.8 – Date Of Service (DOS) for Clinical Lab and Path Specimens

• The DOS for either a clinical laboratory or the technical component of physician pathology service is as follows (cont.):
  – **Exceptions**: Two exceptions apply to DOS policy for either a clinical lab test or the technical component of physician pathology service:
    • A. DOS for Tests/Services Performed on Stored Specimens:
      – If a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS must be date the test/service was performed only if:
        » The test/service is ordered by patient’s physician at least 14 days following the date of patient’s discharge from hospital;
        » Specimen was collected while patient was undergoing a hospital surgical procedure;
        » It would be medically inappropriate to have collected the sample other than during the hospital procedure for which patient was admitted;
        » Results of the test do not guide treatment provided during hospital stay; and
        » Test was reasonable and medically necessary for treatment of an illness.
      – If specimen was stored for more than 30 calendar days before testing, it is considered to have been archived and the DOS must be date the specimen was obtained from storage.

(Medicare Claims Processing Manual, 2015)
Section 50.2 – Physician

• If a claim or physician's bill raises a question as to the source of a lab test and it cannot be resolved from available information, carriers must request the source of the lab services from physician.
• If clinical lab test is subject to lab fee schedule, carriers must pay only the person or entity that performed or supervised the performance of the test.
  – However, carriers may also pay one physician for tests performed or supervised by another physician with whom he/she shares a practice, (i.e. the two physicians are members of a medical group whose physicians submit claims in their own names rather than in the name of the group.)
  – Where the medical group submits claims in the name of the group for services of the physician who performed or supervised the performance of these tests, carriers must pay the group.
  – Regardless of who submits claim, assignment is required for payment.

(Medicare Claims Processing Manual, 2015)

Section 60.1 Specimen Collection Fee

In addition to amounts provided in fee schedules, the Secretary shall provide for and establish a nominal fee to cover appropriate cost of collecting sample on which a clinical lab test was performed and for which payment is made with respect to samples collected in the same encounter.

– A specimen allowance fee is allowed in circumstances such as drawing a blood sample through venipuncture or collecting a urine sample by catheterization.

– A specimen collection fee is not allowed for blood samples where the cost of collecting the specimen is minimal (such as a throat culture or routine capillary puncture for clotting or bleeding time).

– This fee will not be paid to anyone who has not extracted the specimen.

– Only one collection is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn.

– When a series of specimens are required to complete a single test (eg, glucose tolerance test), the series is treated as a single encounter.

(Medicare Claims Processing Manual, 2015)
Section 60.1.4 Coding Requirements for Specimen Collection

- The following HCPCS codes and terminology must be used:
  - 36415 – Collection of venous blood by venipuncture
  - G0471 – Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a lab on behalf of a home health agency.
  - P9615 – Catheterization for collection of specimen(s)
- The allowed amount for specimen collection in each of the above circumstances is included in the laboratory fee schedule distributed annually by CMS.

(Medicare Claims Processing Manual, 2015)

Section 80.2 – Anatomic Pathology Services

- Clinical labs tests include some services described as anatomic pathology services in CPT (i.e., certain cervical, vaginal, or peripheral blood smears).
  - The CPT code 85060 is used only when a physician interprets an abnormal peripheral blood smear for a hospital inpatient or hospital outpatient, and the hospital is responsible for the TC.
    - When an independent lab bills a physician interp of an abnormal peripheral blood smear, the service is considered a complete or global services, and is not billed with CPT code 85060.
    - A physician interpretation of an abnormal peripheral blood smear performed by an independent lab is considered a routine part of the ordered hematology service (i.e. those test that include a different white blood count)
  - HCPCS code 88150 (cervical or vaginal smears) included both screening and interpretation in CPT 1986 terminology while CPT 1987 includes only screening.
    - A new code 88151, was added for those smears that require physician interpretation. Code 88151 is treated and priced in the same manner as code 88150 was previously treated and priced.
    - Code 88151 with a “26” modifier is paid when a physician performs an interp of an abnormal smear for a hospital inpatient or outpatient, and the hospital is responsible for the TC.

(Medicare Claims Processing Manual, 2015)
Section 120.1 Physician Reporting Diagnosis Codes When a Diagnostic Test Is Ordered

- Section 4317 of Balance Budget Act of 1997:
  - Provides, with respect to diagnostic lab and certain other services that “if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the services to provide a diagnostic or other medical information to the entity, the physician, or practitioner ordering the service shall provide that information to the entity at the time the service is ordered by the physician or practitioner”.
  - A lab or other provider must report on a claim for Medicare payment the diagnostic code(s) furnished by the ordering physician. In the absence of such coding information, the lab or other provider may determine appropriate diagnosis code based on the order physician’s narrative diagnostic statement or seek diagnostic information from the ordering physician.
  - However, a lab or other provider may not report on a claim for Medicare payment a diagnosis code in the absence of physician-supplied diagnostic information supporting such code.

(Medicare Claims Processing Manual, 2015)

Clarification of the Use of the Term “Screening” Or “Screen”

- Final Rule effective 02/21/02 clarifies:
  - Use of the term “screening” or “screen” in CPT code descriptor does not necessarily describe a test performed in the absence of signs and symptoms, disease or condition. Contractors do not deny a service based solely on the presence of the term “screening” or “screen” in the descriptor.
  - Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described.
  - If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. Contractors have discretionary authority to make reasonable and necessary scope of benefit determination.
Diagnostic Coding and Reporting Guidelines for Outpatient Services

• From ICD-10-CM Official Guidelines for Coding and Reporting 2016:
  – A. Selection of first-listed condition
    • In outpatient setting, the term first-listed diagnosis is used in lieu of principal diagnosis.
    • In determining first-listed diagnosis, coding conventions, as well as general disease specific guidelines take precedence over the outpatient guidelines.
    • For accurate reporting of ICD-10 codes, the documentation should describe patient’s condition, using terminology which includes specific diagnoses as well as symptoms, problems, or reasons for the encounter.

ICD-10-CM Coding for Pathology and Laboratory

• For patients receiving diagnostic services only during an encounter/visit:
  – Sequence first the diagnosis, condition, problem, or other reason for encounter/visit shown in medical record to be chiefly responsible for services.
  – Other diagnoses (eg, chronic conditions) may be sequenced as additional diagnoses.
  – For encounters for routine laboratory/radiology testing in the absences of signs and symptoms, or associated diagnosis, assign Z01.89 – Encounter for other specified special examinations.
  – If routine testing is performed during the same encounter as a test to evaluate sign, symptom, or diagnosis, it is appropriate to assign both the Z code and the code describing the reason for the non-routine test.
  – For outpatient encounters for diagnostic tests that have been interpreted by a physician, and the final report is available at the time of coding, code any confirmed or definitive diagnosis(es) documented in the interpretation. Do not code related signs and symptoms as additional diagnosis.
ICD-10-CM Coding for Pathology and Laboratory

• For routine well visits, code any abnormalities found such as:
  – Abnormality discovered on screening Pap test
  – Follow any other instructions such as "Use additional code" (eg, estrogen receptor status – Z17.0 or Z17.1)

ICD-10 Codes Cannot Be Changed at Patient’s Request

• Occurs often with screening procedures – i.e. colonoscopy
  – Carrier pays 100% if screening
  – Deductible and coinsurance apply to diagnostic
  – Get patient and insurance carrier on phone is dispute – sometimes insurance carrier changes answer they originally provided to patient
  – Only change if you have written permission for the insurer and documentation substantiates (with amendment, if necessary)
ICD-10-CM Coding for Neoplasms

• Neoplasm Table – Classification based on morphology
  – Malignant primary – origin of malignancy – originates in site where found
  – Malignant secondary – malignancy has spread – metastatic from primary site
  – Carcinoma in situ – Contained within the epithelial tissue; encapsulated;
  – Benign – non-malignant; favorable prognosis
  – Neoplasm of uncertain behavior – uncertain – can’t be classified at this time in any other category
  – Neoplasm of unspecified behavior – unspecified – no classification given in medical report

Case Study – Neoplasm Coding

Clinical Diagnosis: lung mass
Pathologic Diagnosis: primary adenocarcinoma
Specimen(s) Received: right lung biopsy
1. Start with final pathologic diagnosis.
2. Look up final diagnosis in the Alphabetic Index. If uncertain as to meaning of term, look up term in Index.
   – Adenocarcinoma – ICD-10 will show “See Neoplasm by site, malignant.
   – Go to Neoplasm Table and look up Lung, lobe NEC, under malignant primary column, coder will be lead to code C34.9-
3. Tabular List: C34.91 – Malignant neoplasm of unspecified part of right bronchus or lung.
4. Look at instructional notes – states “Use additional code to identify tobacco use, exposure to ..., etc.
5. Refer to any other Notes at Category and Sub-category codes as well an any Includes, Excludes1, Excludes2 indicators.
6. Additional questions to consider:
   – Would it be worthwhile for reimbursement purposes to research the EMR to identify the lobe of the lung that was biopsied?
   – Why do we need to code the additional risk of tobacco use?

(Padget & Cox, 2015)
Neuroendocrine Tumors

• Carcinoid tumors:
  – Malignant neuroendocrine tumors – C7A-
  – Secondary neuroendocrine tumors – C7B-
  – Benign neuroendocrine tumor – D3A-
  – Not in Neoplasm Table
  – Many are of uncertain behavior
  – Pathologist – suggested to document malignant or benign when possible and document in medical record

ICD-10-CM Coding of Neoplasms

• Primary malignant neoplasm that overlaps two or more contiguous (next to each other) sites should be classified to the subcategory .8 (“overlapping lesion”), unless the combination is specifically indexed elsewhere.
• For multiple neoplasms of the same site that are not contiguous such as tumors in different quadrants of the same breast, code for each site should be assigned:
• Example from ICD-10-CM Expert for Physicians 2016 published by Optum in the Tabular List, page 444:
  • “A 73 year old female with a large, rapidly growing tumor in the left breast extending from the upper outer quadrant into to axillary tail.”
    – Code as: “C50.812 – Malignant neoplasm of overlapping sites of left female breast.
    – “Explanation: Because this is a single large tumor that overlaps two contiguous sites, a single code for overlapping sites is assigned.”
Malignant Tissue of Ectopic Tissue

- Malignant neoplasms of ectopic tissue are to be coded to the site of origin mentioned, eg, ectopic pancreatic malignant neoplasms involving the stomach are coded to the pancreas, unspecified (C25.9)

Treatment Directed at the Malignancy

- ICD-10-CM Official Guidelines for Coding and Reporting 2016:
  - “If the treatment is directed at the malignancy, designate the malignancy as the principal diagnosis.
  - The only exception to this guideline is if a patient admission/encounter is solely for the administration of chemotherapy, immunotherapy, or radiation therapy, assign the appropriate Z51.- code as the first listed or principal diagnosis, and the diagnosis or problem for which the service is being performed as the secondary diagnosis.”
  - “When a patient is admitted because of a primary neoplasm with metastasis and treatment is directed at the secondary site only, the secondary neoplasm is designated as the principal diagnosis even though the primary malignancy is still present.”
ICD-10-CM Coding for a Primary Malignancy that Has Been Previously Excised

• “When a primary malignancy has been excised or eradicated from its site and there is no further treatment directed to that site and there is no evidence of any existing primary malignancy, a code from category Z85, Personal history of malignant neoplasm, should be used to indicate the former site of the malignancy.”

• “Any mention of extension, invasion, or metastasis to another site is coded as a secondary malignant neoplasm to that site. The secondary site may be the principal or first-listed code with the Z85 code used as a secondary code.”

Symptoms, Signs and Abnormal Findings Listed In Chapter 18 Associated with Neoplasms

“Symptoms, signs, and ill-defined conditions listed in Chapter 18 characteristic of, or associated with, an existing primary or secondary site malignancy cannot be used to replace the malignancy as principal or first-listed diagnosis, regardless of the number of admissions or encounters for treatment and care of the neoplasm.”
### ICD-10-CM Coding for Pap Testing

- **Alphabetic Index – Abnormal; Papanicolaou (smear)**
  - Anus R85.619
    - Atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H) R85.611
    - Atypical squamous cells of undetermined significance (ASC-US) R85.610
    - Cytological evidence of malignancy R85.614
    - High grade squamous intraepithelial lesion (HGSIL) R85.613
    - Human papillomavirus (HPV) DNA test
      - High risk positive R85.81
      - Low risk positive R85.82
      - Inadequate smear R85.615
      - Low-grade squamous intraepithelial lesion (LGSIL) R85.612
      - Satisfactory anal smear but lacking transformation zone R85.616
      - Specified NEC R85.618
      - Unsatisfactory smear R85.618
  - Bronchial washings R84.6......
  - Cervix R87.619
    - Atypical

### Skin and Skin Cancers

- The skin is the largest organ in the human body and has many different functions.
  - **Epidermis:** The top layer of the skin is very thin, averaging only about 1/100 of an inch thick.
  - **Main types of cells in the epidermis:**
    - Squamous cells – Flat cells in the outer part of the epidermis that are constantly shed as new ones form.
      - Around 2 out of 10 skin cancers are squamous cell carcinoma. Commonly appear on sun-exposed area. Sometimes begin a actinic keratosis also known as solar keratosis – a pre-cancerous condition. These are usually small, rough or scaly spots that may be pink-red or flesh-colored which grow slowly and usually do not cause any symptoms.
Integumentary System

- The skin is the largest organ in the human body and serves many functions.
- Epidermis – top layer of skin; very thin, averaging only about 1/100 of an inch thick; protects deeper layers of skin.
- Main types of cell in epidermis:
  - Squamous cells – flat cells in the outer part of epidermis that are constantly shed as new ones form.
  - About 2 out of 10 skin cancers are squamous cell carcinoma – also called squamous cell cancers. Commonly appear on sun-exposed areas of body such as face, ears, neck lips and backs of hands.
  - Squamous cell cancers are more likely to grow into deeper layers of skin and spread to other parts of the body than basal cell cancers, although this is still common.

ICD–10–CM Codes Covered by Medicare Program

- This section includes ‘covered’ codes – that is, codes for those lab test services for which Medicare provides the presumption of medical necessity, but may review a claim for such services to determine whether the service was in fact reasonable and necessary.
- The ‘covered’ diagnosis codes are from the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM).
- Where the policy takes an “exclusionary” approach, as described below, this section states: “Any ICD–10–CM code not listed in either of the ICD–10–CM code sections below.”
Providers’ Obligation for Reporting Diagnostic Codes to Payers

• Medicare – Section 1842(p)(4) of Social Security Act:
  – “In the case of an item or service…ordered by a physician or practitioner…but furnished by another entity,…the physician or practitioner shall provide the appropriate diagnosis code(s) to the entity at the time that the item or service is ordered…”

Pathologist and Lab

• Must supply ICD code(s) on claim for services:
• Section 1842(p)(1) of Social Security Act:
  – “Each request for payment…for an item or service…for which payment may be made under (Medicare Part B) shall include the appropriate diagnosis code(s)…for such item or service.
  – Order/referring physician – Who ordered? Why ordered? Information must be provided to by ordering/referring to indicate medical necessity of testing for condition(s)/symptoms.
Clinical Lab

• Payment via Clinical Lab Fee Schedule:
  – MCPM, Chapter 16, Paragraph 120.1:
    • “A laboratory...must report...the diagnostic code(s) furnished by the ordering physician.”
    • “A laboratory... May not report...a diagnosis code in the absence of physician-supplied diagnostic information support such code.”
    • Secondary diagnosis code(s) may be added by the lab based on test results.
    • Pap test, molecular tests and cytogenetics tests are subject to “clinical diagnosis first” Medicare rule:
      – Rule applies even to pathologist interpreted CLFS tests
      – Different rule may apply to pathologist interpretation claim (if any)
      – Screening ICD code remains first-listed even if test result is abnormal.

Services Paid by PFS

• MCPM, Chapter 23, P 101.1(A) pre-2014:
  – “If the physician has confirmed a diagnosis based on the results of diagnostic test, the physician interpreting the test should code that diagnosis.”
  – “The clinical diagnosis that prompted ordering the test may be reported as additional diagnosis if it is not fully explained or related to the confirmed diagnosis”.
  – “First-listed (principal) diagnosis is the clinical diagnosis, if a definitive pathologic diagnosis is not available at the time the claim is filed:
    • If the diagnostic test did not provide a diagnosis..., the interpreting physician should code the sign or symptoms that prompted the treating physician to order the study.” (MCPM, chapter 23, P 10.1.1(B) pre-2014/
Reporting ICD-10 Codes

- ICD-10-CM and Medicare support the reporting of one diagnosis code based on specimens examined.
  - Report ICD-10-CM code that describes the patient’s most significant or complex condition except:
    - On a case-by-case basis for some bilateral specimens (eg, breast, lung) and major resections (eg, cystoprostatectomy)

Reasons for Denial for All Lab NCDs

**NOTE:** This section includes CMS’s interpretation of its longstanding policies pertaining to nationally covered laboratory services, and is included for informational purposes.

- Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute.
  - **Tests for administrative purposes**, including exams required by insurance companies, business establishments, government agencies, or other third parties, are not covered.
  - **Tests that are not reasonable and necessary** for the diagnosis or treatment of an illness or injury are not covered by statute.
  - **Failure to provide documentation of the medical necessity of tests** might result in denial of claims. The documentation may include notes documenting relevant signs, symptoms, or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, **failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician’s office might result in denial.**

*(Clinical Diagnostic Laboratory Services, 2014)*
Reasons for Denial for All Lab NCDs

– A claim for a test for which there is a national coverage policy will be denied as not reasonable and necessary if the claim is submitted without an ICD-10-CM code or narrative diagnosis listed as covered in the policy unless other medical documentation justifying the necessity is submitted with the claim.

– If a national coverage policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary, unless it is submitted with documentation justifying increased frequency.

– Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.

– Failure of the clinical laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate will result in denial of claims.

(Clinical Diagnostic Laboratory Services, 2014)

Coding Guidelines for All Lab NCDs

1. For ICD-10-CM coding of Medicare billing claims, a claim for a clinical diagnostic laboratory service must include a valid ICD-10-CM diagnosis code. When a diagnosis has not been established by the physician, codes that describe symptoms and signs, as opposed to diagnoses, should be provided.

2. Medicare distinguishes screening from diagnostic uses of tests.

   – Screening is testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present and the beneficiary has not been exposed to a disease.

   – In contrast, diagnostic testing is testing to rule out or to confirm a suspected diagnosis because of a sign and/or symptom in the beneficiary. In these cases, the sign or symptom should be used to explain the reason for the test. Some laboratory tests are covered by the Medicare program for screening purposes
Coding Guidelines for All Lab NCDs

3. When the reason for performing a test is because the beneficiary has had contact with, or exposure to, a communicable disease, the appropriate code from category Z20, ‘Contact with or exposure to communicable diseases,’ should be assigned. However, on review, the test might still be considered screening and not covered by Medicare.

4. All digits required by ICD-10-CM coding conventions must be used. A code is invalid if it has not been coded with all digits/characters required for that code.

5. The beneficiary’s condition(s) and/or diseases should be coded in ICD-10-CM to the highest degree of certainty for that encounter/visit, such as signs, symptoms, abnormal test results, or other reasons for the visit. When a non-specific ICD-10-CM code is submitted, the underlying sign, symptom, or condition must be related to the indications for the test.

Toxicology Coding

- Is the physician testing for potential drug abuse, or is the clinician monitoring therapeutic levels of known drugs?
- Drugs of abuse – If the testing is to screen for, or identify potential drug abuse- Will use CPT section “Drug Assay” which is divided into two subsections:
  - Presumptive Drug Class Screening – (Drug screen…) to see if patient possibly did or did not use drug(s) in specific classes. These tests don’t identify a specific drug, and can’t distinguish between structural isomers (such as morphine and hydromorphone). Clinicians may order additional testing based on presumptive test results.
  - Definitive Drug Testing – Test are more specific than the presumptive and can identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers). Clinicians may order these as the first test, or as a confirmatory test following a positive screening test.
Controlled Substance Monitoring and Drugs of Abuse – Palmetto GBA

• Coding and Billing Guidelines
  – Effective 01/01/2016, controlled substance testing providers should apply the following guidelines:
    • To receive reimbursement, the service reported on the claim must match the service ordered by the physician.
    • Incidental findings not ordered are not a covered service and will be denied.
    • A maximum of one presumptive urine drug test may be submitted and paid per patient encounter.
    • A maximum of one definitive urine drug test may be submitted and paid per encounter.

Presumptive Drug Testing (UDT)

• Providers may only perform and report one of the following three types of presumptive test:
  1. **HCPCS code G0477** – Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay) capable of being by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.
  2. **HCPCS code G0478** – Drug test(s), presumptive, any number of drug classes; any number of devices or procedures (eg, immunoassay) read by instrument-assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.
  3. **HCPCS code G0479** – Drug test(s), presumptive, any number of drug classes, any number of devices or procedures by instrumented chemistry analyzers (eg, immunoassay, enzyme assay, TOF, MALDI, LDTD, DSEI, DART, GHPC, GC mass spectrometry), includes sample validations when performed, performed, per date of service.
Definitive (Qualitative or Quantitative) UDT Testing

- Based on the number of drug classes indicated for patient's needs, providers may only perform and report one of the following four UDT services per patient encounter:
  - 1. HCPCS code – G0480 – Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereosomers), but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase), qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug classes), including metabolite(s) if performed.
  - 2. HCPCS code – G0481 – ....per day 8-14 drug class(es)....
  - 3. HCPCS code – G0482 – ....per day, 15-21 drug class(es)....
  - 4. HCPCS code – G0483- ....per day, 22 or more drug classes....

Coding/Billing Clarification of Non-Covered Services

- Reflex testing for IA presumptive positives may only be performed by laboratories other than physician office labs (POL). Physicians in POL are expected to determine the medical necessity for definitive testing for a presumptive positive result, and document the necessity in the medical record because they have specific patient information and may not need definitive testing.
- When a presumptive test is negative for a patient on a prescribed medication, a definitive drug test may be performed.
- Only one presumptive service may be billed per patient, per encounter, regardless of the provider.
- Medicare will process the first presumptive service received per patient, per encounter. All subsequent claims will be denied.
- Only one definitive service may be billed per patient, per encounter, regardless of the provider.
- Medicare will process the first definitive service received per patient, per encounter. All subsequent will be denied.
Questions?

• Thank you for your attendance!

• Get your questions answered on PMI’s Discussion Forum:
  http://www.pmimd.com/pmiForums/rules.asp

• Contact: mcollins@pmimd.com

References


References


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