DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Calendar Year (CY) 2016 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

Provider Types Affected

This MLN Matters® article is intended for clinical diagnostic laboratories that submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9465 provides instructions for the CY 2016 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. Make sure your billing staffs are aware of these updates.

Background

In accordance with Section 1833(h)(2)(A)(i) of the Social Security Act (the Act), the annual update to the local clinical laboratory fees for CY 2016 is 0.10 percent. The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2016 is 0.10 percent (See **42 CFR 405.509(b)(1)**). Section 1833(a)(1)(D) of the Act provides that payment for a clinical laboratory test is the lesser of the actual charge billed for the test, the local fee, or the National Limitation Amount (NLA).The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

Key Points of CR 9465

National Minimum Payment Amounts
For a cervical or vaginal smear test (pap smear), Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount. Further, payment may not exceed the actual charge. The CY 2016 national minimum payment amount is $14.39 ($14.38 times 0.10 percent update for CY 2016). The affected codes for the national minimum payment amount are 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

National Limitation Amounts (Maximum)
For tests for which NLAs were established before January 1, 2001, the NLA is 74 percent of the median of the local fees. For tests for which the NLAs are first established on or after January 1, 2001, the NLA is 100 percent of the median of the local fees in accordance with Section 1833(h)(4)(B)(viii) of the Act.

Access to Data File
Internet access to the CY 2016 clinical laboratory fee schedule data file is available at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched** on the Centers for Medicare & Medicaid (CMS) website. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board may use the Internet to retrieve the CY 2016 clinical laboratory fee schedule; available in multiple formats: Excel, text, and comma delimited.

Public Comments and Final Payment Determinations
On July 16, 2015, CMS hosted a public meeting to solicit input on the payment relationship between CY 2015 codes and new CY 2016 CPT codes. Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations on the website at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html** on the CMS website. Additional written comments from the public were accepted until October 26, 2015. CMS has posted a summary of the public comments and the rationale for the final payment determinations at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2016-CLFS-Codes-Final-Determinations.pdf** on the CMS website.

Pricing Information
The CY 2016 clinical laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees have been established in accordance with Section 1833(h)(4)(B) of the Act.

The fees for clinical laboratory travel codes P9603 and P9604 are updated on an annual basis. The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for CY 2016, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2016 clinical laboratory fee schedule also includes codes that have a "QW" modifier to both identify codes and determine payment for tests performed by a laboratory having only a certificate of waiver under the Clinical Laboratory Improvement Amendments (CLIA).

Organ or Disease Oriented Panel Codes

Similar to prior years, the CY 2016 pricing amounts for certain organ or disease panel codes and evocative/suppression test codes were derived by summing the lower of the clinical laboratory fee schedule amount or the NLA for each individual test code included in the panel code. The NLA field on the data file is zero-filled.

Mapping Information

New code G0477 is priced at the same rate as 0.75 times code G0434.

New code G0478 is priced at the same rate as code G0434.

New code G0479 is priced at the same rate as 4.00 times code G0434.

New code G0480 is priced at the same rate as 3.25 times code 82542.

New code G0481 is priced at the same rate as 5.00 times code 82542.

New code G0482 is priced at the same rate as 6.75 times code 82542.

New code G0483 is priced at the same rate as 8.75 times code 82542.

New code 87651QW is priced at the same rate as code 87651.

New code 87806QW is priced at the same rate as code 87806.

New code 87502QW is priced at the same rate as code 87502.

New code 86780QW is priced at the same rate as code 86780.

New code 87650QW is priced at the same rate as code 87650.

New code 87389QW is priced at the same rate as code 87389.

New code 86850 is priced at the same rate as code 86902.

New code 80081 is priced at the same rate as the sum of codes 85025, 87340, 87389, 86762, 86592, 86850, 86900, and 86901.

New code 80055 is priced at the same rate as the sum of codes 85025, 87340, 86762, 86592, 86850, 86900, and 86901.

New code G0472 is priced at the same rate as code 86803.

New code G0472QW is priced at the same rate as code 86803.

New code 81162 is priced at the same rate as the sum of 0.90 times code 81211, and 0.90 times code 81213.

New code 81170 is priced at the same rate as code 81235.

New code 81218 is priced at the same rate as code 81235.

New code 81219 is priced at the same rate as code 81245.

New code 81272 is priced at the same rate as code 81235.

New code 81273 is priced at the same rate as code 81270.

New code 81276 is priced at the same rate as code 81275.

New code 81311 is priced at the same rate as 1.50 times code 81275.

New code 81314 is priced at the same rate as code 81235.

New code 81528 is priced at the same rate as the sum of codes 81315, 81275, and 82274.

New code 81535 is priced at the same rate as the sum of 2.00 times code 88239 and code 87900.

New code 81536 is priced at the same rate as code 87900.

New codes to be gap filled are: 81412, 81432, 81433, 81434, 81437, 81438, 81442, 81490, 81493, 81525, 81538, 81540, 81545, 81595, 0009M, and 0010M.

The following existing codes are to be deleted: G0431, G0434, G0434QW, G0464, G6030, G6031, G6032, G6034, G6035, G6036, G6037, G6038, G6039, G6040, G6041, G6042, G6043, G6044, G6045, G6046, G6047, G6048, G6049, G6050, G6051, G6052, G6053, G6054, G6055, G6056, G6057, G6058, 82486, 82487, 82488, 82489, 82491, 82492, 82541, 82543, 82544, and 83788.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2011

For outpatients, the following codes are paid under a reasonable charge basis (See Section 1842(b)(3) of the Act). In accordance with 42 CFR 405.502 through 42 CFR 405.508, the reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index for the 12-month period ending June 30 of each year as set forth in 42 CFR 405.509(b)(1). The inflation-indexed update for CY 2016 is 0.1 percent.

Manual instructions for determining the reasonable charge payment are available in the "Medicare Claims Processing Manual," **Chapter 23** (Fee Schedule Administration and Coding Requirements), Sections 80 through 80.8. If there is sufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

When services described by the Healthcare Common Procedure Coding System (HCPCS) in the following list are performed for independent dialysis facility patients, "Medicare Claims Processing Manual," **Chapter 8** (Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims), Section 60.3, instructs that the reasonable charge basis applies. However, when these services are performed for hospital-based renal dialysis facility

patients, payment is made on a reasonable cost basis. Also, when these services are performed for hospital outpatients, payment is made under the hospital Outpatient Prospective Payment System (OPPS).

Blood Product Codes
Blood Product codes are: P9010, P9011, P9012, P9016, P9017, P9019, P9020, P9021, P9022, P9023, P9031, P9032, P9033, P9034, P9035, P9036, P9037, P9038, P9039, P9040, P9044, P9050, P9051, P9052, P9053, P9054, P9055, P9056, P9057, P9058, P9059, and P9060.

Also, payment for the following codes should be applied to the blood deductible as instructed in the "Medicare General Information, Eligibility and Entitlement Manual," **Chapter 3** (Deductibles, Coinsurance Amounts, and Payment Limitations), Sections 20.5 through 20.5.4: P9010, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9057, and P9058.

NOTE: Biologic products not paid on a cost or prospective payment basis are paid based on Section 1842(o) of the Act. The payment limits based on Section 1842(o), including the payment limits for codes P9041, P9045, P9046, and P9047, should be obtained from the Medicare Part B drug pricing files.

Transfusion Medicine Codes
Transfusion Medicine codes are: 86850, 86860, 86870, 86880, 86885, 86886, 86890, 86891, 86900, 86901, 86902, 86904, 86905, 86906, 86920, 86921, 86922, 86923, 86927, 86930, 86931, 86932, 86945, 86950, 86960, 86965, 86970, 86971, 86972, 86975, 86976, 86977, 86978, and 86985.

Reproductive Medicine Procedure Codes
Reproductive Medicine Procedure codes are: 89250, 89251, 89253, 89254, 89255, 89257, 89258, 89259, 89260, 89261, 89264, 89268, 89272, 89280, 89281, 89290, 89291, 89335, 89342, 89343, 89344, 89346, 89352, 89353, 89354, and 89356.

Your MAC will not search their files to either retract payment or retroactively pay claims; however, should adjust claims that you bring to their attention.

Additional Information

The official instruction, CR9465 issued to your MAC regarding this change is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3420CP.pdf** on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html** under - How Does It Work.