

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4208	Date: January 17, 2019
	Change Request 11076

Transmittal 4182, dated December 14, 2018, is being rescinded and replaced by Transmittal 4208, dated, January 17, 2019 to remove code 0008U from the list of revised codes effective January 1, 2019. All other information remains the same.

SUBJECT: Calendar Year (CY) 2019 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the CY 2019 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: January 1, 2019

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 7, 2019

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

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I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the CY 2019 clinical laboratory fee schedule (CLFS), mapping for new codes for clinical laboratory tests, updates for laboratory costs subject to the reasonable charge payment, and other CLFS related information. This RUN applies to chapter 16, section 20.

B. Policy:

Protecting Access to Medicare Act of 2014 (PAMA) Updates

- Next CLFS Data Collection Period

Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. The CLFS final rule “Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule” (CMS-1621-F) was published in the **Federal Register** on June 23, 2016. The CLFS final rule implemented section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The next data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) is from January 1, 2019 through June 30, 2019, and the next 6-month window is July 1, 2019 and ending December 31, 2019 (the period where laboratories and reporting entities assess whether the applicable laboratory thresholds are met and review and validate applicable information before it is reported to CMS). The next data reporting period is January 1, 2020 through March 31, 2020, where applicable information is reported to CMS. This data will be used to calculate revised private payor rate-based CLFS rates effective January 1, 2021. Specific directions on data collection and data reporting can be found here: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html>.

- Revisions to the Definition of Applicable Laboratory

The Physician Fee Schedule (PFS) final rule entitled “Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019” (CMS-1693-F) was displayed in the **Federal Register** on November 1, 2018 and was published on November 23, 2018. In the CY 2019 PFS final rule, CMS made two revisions to the regulatory definition of applicable laboratory: 1) Effective January 1, 2019, Medicare Advantage plan revenues are excluded from total

Medicare revenues (the denominator of the majority of Medicare revenues threshold); and (2) Effective January 1, 2019, hospitals that bill for their non-patient laboratory services may use Medicare revenues from the Form CMS 1450 14x Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

Effective January 1, 2019, the regulatory definition of an applicable laboratory is summarized below (revisions are annotated by italics font).

Applicable laboratory means an entity that:

(1) Is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory (42 C.F.R. § 493.2);

(2) The laboratory bills Medicare under its own National Provider Identifier (NPI) *or*

(i) For hospital outreach laboratories --bills Medicare Part B on the Form CMS 1450 under bill type 14x;

(3) The laboratory must meet a “majority of Medicare revenues” threshold, where it receives more than 50 percent of its total Medicare revenues from one or a combination of the CLFS or the PFS in a data collection period.

For purposes of determining whether a laboratory meets the “majority of Medicare revenues” threshold, total Medicare revenues includes: fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance.

Effective January 1, 2019, total Medicare revenues no longer includes Medicare Advantage payments under Medicare Part C.

(4) The laboratory must meet a “low expenditure” threshold, where it receives at least \$12,500 of its Medicare revenues from the CLFS in a data collection period.

As noted above, the next CLFS data collection period will be January 1, 2019 through June 30, 2019. All hospital outreach laboratories that bill for non-patient laboratory services using the Form CMS 1450 14x TOB, will be required to determine applicable laboratory status from its final paid Medicare claims received during the next data collection period. Hospital outreach laboratories that meet the definition of an applicable laboratory will be required to report applicable information to CMS during the next data reporting period, which is January 1, 2020 through March 31, 2020. Additional sub regulatory guidance will be made available on the CLFS website under the PAMA regulations tab: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html>.

- Coding for Healthcare Common Procedure Coding System (HCPCS) Panel Codes

As laboratories are aware, the implementation of PAMA required Medicare to pay the weighted median of private payor rates for each separate HCPCS code. Prior to PAMA implementation, CMS paid for certain chemistry tests using Automated Test Panels (ATPs) which used claims processing logic to apply a bundled rate to sets of these codes, depending on how many of these chemistry tests were ordered. Additionally, the

claims processing system would not pay more than the associated panel CPT code if the tests were billed individually. This logic no longer exists under PAMA guidelines. HCPCS codes include those from the AMA Current Procedural Terminology (CPT) Manual, that are in the category of Organ or Disease Oriented panels, which are panels that consist of groups of specified tests. Because CMS no longer has payment logic to roll up panel pricing, laboratories shall report the panel test where appropriate and not report separately the tests that make up that panel. This is also consistent with recent changes in CMS's National Correct Coding Initiative (NCCI) manual. For example, if the individually ordered tests are cholesterol (CPT code 82465), triglycerides (CPT code 84478), and HDL cholesterol (CPT code 83718), the service shall be reported as a lipid panel (CPT code 80061). If the laboratory repeats one of these component tests as a medically reasonable and necessary service on the same date of service, the CPT code corresponding to the repeat laboratory test may be reported with modifier 91 appended. For additional information on coding for these codes, please refer to the NCCI Policy Manual for Medicare Services for CY 2019 (<https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html>):

- Chapter I, Section N (Laboratory Panel);
- Chapter X, Section C (Organ or Disease Oriented Panels)

Update to Fees

In accordance with Section 1833(h)(2)(A)(i) of the Act, the annual update to the local clinical laboratory fees for CY 2019 is 2.30 percent. Beginning January 1, 2019, this update applies only to pap smear tests. For a pap smear test, Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the National Limitation Amount, but not less than a national minimum payment amount. However, for pap smear tests, payment may also not exceed the actual charge. The CY 2019 national minimum payment amount is \$14.99 (This value reflects the CY 2018 national minimum payment with a 2.3 percent increase or \$14.65 times 1.0230). The affected codes for the national minimum payment amount are: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, Q0111, Q0115, and P3000.

The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2019 is 2.3 percent (See 42 CFR 405.509(b)(1)).

The Part B deductible and coinsurance do not apply for services paid under the CLFS.

Access to Data File

The CY 2019 CLFS data file shall be retrieved electronically through CMS' mainframe telecommunications system. A/B MAC contractors shall retrieve the data file on or after December 1, 2018. Internet access to the CY 2019 CLFS data file shall be available after December 1, 2018, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>. Other interested parties shall use the Internet to retrieve the CY 2019 CLFS. It will be available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 25, 2018, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2018 codes and new CY 2019 CPT codes. Notice of the meeting was published in the **Federal Register** on March 30, 2018. 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 web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html. Additional written comments from the public were accepted until October 22, 2018. CMS also posted a summary of the public comments and the rationale for the final payment determinations at the same CMS web site identified in the previous sentence.

Pricing Information

The CY 2019 CLFS 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 2019, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2019 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 CLIA certificate of waiver.

Mapping Information

Reconsidered code 81326 is priced at the same rate as code 81322.

Reconsidered code 81334 is priced at the same rate as code 81272.

New code 0011M is priced at the same rate as code 0005U.

New code 0012M is priced at the same rate as code 0005U.

New code 0013M is priced at the same rate as code 0005U.

New code 0018U is to be gapfilled.

New code 0019U is to be gapfilled.

New code 0020U is to be deleted.

New code 0021U is to be gapfilled.

New code 0022U is to be gapfilled.

New code 0023U is to be gapfilled.

New code 0024U is priced at the same rate as code 83704.

New code 0025U is priced at the same rate as code G0480.

New code 0026U is priced at the same rate as code 81545.

New code 0027U is priced at the same rate as 1.33 times code 0017U.

New code 0028U is to be deleted.

New code 0029U is to be gapfilled.

New code 0030U is to be gapfilled.

New code 0031U is priced at the same rate as code 81227.

New code 0032U is priced at the same rate as code 81230.

New code 0033U is priced at the same rate as 2 times code 81230.

New code 0034U is priced at the same rate as code 81225 plus code 81335.

New code 0035U is to be gapfilled.

New code 0036U is priced at the same rate as code 81415.

New code 0038U is priced at the same rate as code 82306.

New code 0039U is priced at the same rate as code 86225.

New code 0040U is priced at the same rate as 2.5 times code 81206.

New code 0041U is to be gapfilled.

New code 0042U is to be gapfilled.

New code 0043U is to be gapfilled.

New code 0044U is to be gapfilled.

New code 0045U is priced at the same rate as code 81519.

New code 0046U is priced at the same rate as code 81245.

New code 0047U is priced at the same rate as code 81519.

New code 0048U is to be gapfilled.

New code 0049U is priced at the same rate as code 81310.

New code 0050U is to be gapfilled.

New code 0051U is priced at the same rate as code G0483.

New code 0052U is priced at the same rate as code 83701.

New code 0053U is to be gapfilled.

New code 0054U is priced at the same rate as code G0482.

New code 0055U is to be gapfilled.

New code 0056U is to be gapfilled.

New code 0057U is to be gapfilled.

New code 0058U is priced at the same rate as code 86835.

New code 0059U is priced at the same rate as code 86835.

New code 0060U is priced at the same rate as code 81420.

New code 0061U is priced at the same rate as 5 times code 88738.

New code 81345 is priced at the same rate as code 81403.

New code 82642 is priced at the same rate as code 82634.

New code 81333 is priced at the same rate as code 81401.

New code 81596 is priced at the same rate as code 0001M.

New code 81518 is priced at the same rate as code 81519.

New code 81236 is priced at the same rate as code 81406.

New code 81237 is priced at the same rate as code 81210.

New code 81233 is priced at the same rate as code 81210.

New code 81320 is priced at the same rate as code 81225.

New code 81305 is priced at the same rate as code 81210.

New code 81443 is priced at the same rate as code 81412.

New code 81163 is priced at the same rate as code 81406 plus code 81216.

New code 81164 is priced at the same rate as code 81405 plus code 81406.

New code 81165 is priced at the same rate as code 81406.

New code 81166 is priced at the same rate as code 81405.

New code 81167 is priced at the same rate as code 81406.

New code 83722 is priced at the same rate as code 83704.

New code 81306 is priced at the same rate as code 81225.

New code 81171 is priced at the same rate as code 81401.

New code 81172 is priced at the same rate as code 81404.

New code 81204 is priced at the same rate as code 81401.

New code 81173 is priced at the same rate as code 81405.

New code 81174 is priced at the same rate as code 81403.

New code 81177 is priced at the same rate as code 81401.

New code 81178 is priced at the same rate as code 81401.

New code 81183 is priced at the same rate as code 81401.

New code 81179 is priced at the same rate as code 81401.

New code 81180 is priced at the same rate as code 81401.

New code 81181 is priced at the same rate as code 81401.

New code 81182 is priced at the same rate as code 81401.

New code 81184 is priced at the same rate as code 81401.

New code 81185 is priced at the same rate as code 81407.

New code 81186 is priced at the same rate as code 81403.

New code 81187 is priced at the same rate as code 81401.

New code 81188 is priced at the same rate as code 81401.

New code 81189 is priced at the same rate as code 81404.

New code 81190 is priced at the same rate as code 81403.

New code 81234 is priced at the same rate as code 81401.

New code 81239 is priced at the same rate as code 81404.

New code 81284 is priced at the same rate as code 81401.

New code 81285 is priced at the same rate as code 81404.

New code 81286 is priced at the same rate as code 81404.

New code 81289 is priced at the same rate as code 81403.

New code 81271 is priced at the same rate as code 81401.

New code 81274 is priced at the same rate as code 81404.

New code 81312 is priced at the same rate as code 81401.

New code 81329 is priced at the same rate as code 81401.

New code 81336 is priced at the same rate as code 81405.

New code 81337 is priced at the same rate as code 81403.

New code 81343 is priced at the same rate as code 81401.

New code 81344 is priced at the same rate as code 81401.

New code 87634QW is priced at the same rate as code 87634.

Existing code 81211 is to be deleted.

Existing code 81213 is to be deleted.

Existing code 81214 is to be deleted.

Existing code 0001M is to be deleted.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2019

Hospital outpatient claims 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 (CPI) for the 12-month period ending June 30 of each year as set forth in 42 CFR 405.509(b)(1). The CPI update for CY 2019 is 2.90 percent.

Manual instructions for determining the reasonable charge payment can be found in Publication 100-04, Medicare Claims Processing Manual, Chapter 23, Section 80 through 80.8. If there is not sufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

Services described by HCPCS codes in the following list are performed for independent dialysis facility patients. Publication 100-04, Medicare Claims Processing Manual, Chapter 8, 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 Products

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

P9060

P9070

P9071

P9073

P9100

Also, payment for the following codes should be applied to the blood deductible as instructed in Publication 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 3, Section 20.5 through 20.5.4:

P9010

P9016

P9021

P9022

P9038

P9039

P9040

P9051

P9054

P9056

P9057

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

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

86985

Reproductive Medicine Procedures

89250

89251

89253

89254

89255

89257

89258

89259

89260

89261

89264

89268

89272

89280

89281

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89291

89335

89337

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89352

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89354

89356

New Codes Effective October 1, 2018

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of October 1, 2018 and do not need to be manually added to the HCPCS file by the MACs. However, these new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2019 as they were received after the 2018 public meeting

MACs shall only price PLA codes for laboratories within their jurisdiction.

CPT Code: 0062U

Short Descriptor: Ai sle igg&igm alys 80 bmrk

Long Descriptor: Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score

Laboratory: SLE-key® Rule Out, Veracis Inc, Veracis Inc

CPT Code: 0063U

Short Descriptor: Neuro autism 32 amines alg

Long Descriptor: Neurology (autism), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder

Laboratory: NPDX ASD ADM Panel I, Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX

CPT Code: 0064U

Short Descriptor: Antb tp total&rpr ia qual

Long Descriptor: Antibody, Treponema pallidum, total and rapid plasma reagin (RPR), immunoassay, qualitative

Laboratory: BioPlex 2200 Syphilis Total & RPR Assay, Bio-Rad Laboratories, Bio-Rad Laboratories

CPT Code: 0065U

Short Descriptor: Syfls tst nontreponemal antb

Long Descriptor: Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)

Laboratory: BioPlex 2200 RPR Assay, Bio-Rad Laboratories, Bio-Rad Laboratories

CPT Code: 0066U

Short Descriptor: Pamg-1 ia cervico-vag fluid

Long Descriptor: Placental alpha-micro globulin-1 (PAMG-1), immunoassay with direct optical observation, cervico-vaginal fluid, each specimen

Laboratory: PartoSure™ Test, Parsagen Diagnostics, Inc, Parsagen Diagnostics, Inc, a QIAGEN Company

CPT Code: 0067U

Short Descriptor: Onc brst imhchem prfl 4 bmrk

Long Descriptor: Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score

Laboratory: BBDRisk Dx™, Silbiotech, Inc

CPT Code: 0068U

Short Descriptor: Candida species pnl amp prb

Long Descriptor: Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. kruseii, C. tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species

Laboratory: MYCODART Dual Amplification Real Time PCR Panel for 6 Candida species, RealTime Laboratories, Inc

CPT Code: 0069U

Short Descriptor: Onc clrct microrna mir-31-3p

Long Descriptor: Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score

Laboratory: miR-31now™, GoPath Laboratories, GoPath Laboratories

CPT Code: 0070U

Short Descriptor: Cyp2d6 gen com&slct rar vrnt

Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, common and select rare variants (ie, *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10,

*11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *xN)

Laboratory: CYP2D6 Common Variants and Copy Number, Mayo Clinic, Laboratory Developed Test

CPT Code: 0071U

Short Descriptor: Cyp2d6 full gene sequence

Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, full gene sequence (List separately in addition to code for primary procedure)

Laboratory: CYP2D6 Full Gene Sequencing, Mayo Clinic, Laboratory Developed Test

CPT Code: 0072U

Short Descriptor: Cyp2d6 gen cyp2d6-2d7 hybrid

Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D6-2D7 hybrid gene) (List separately in addition to code for primary procedure)

Laboratory: CYP2D6-2D7 Hybrid Gene Targeted Sequence Analysis, Mayo Clinic, Laboratory Developed Test

CPT Code: 0073U

Short Descriptor: Cyp2d6 gen cyp2d7-2d6 hybrid

Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D7-2D6 hybrid gene) (List separately in addition to code for primary procedure)

Laboratory: CYP2D7-2D6 Hybrid Gene Targeted Sequence Analysis, Mayo Clinic, Laboratory Developed Test

CPT Code: 0074U

Short Descriptor: Cyp2d6 nonduplicated gene

Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, non-duplicated gene when duplication/multiplication is trans) (List separately in addition to code for primary procedure)

Laboratory: CYP2D6 trans-duplication/multiplication non-duplicated gene targeted sequence analysis, Mayo Clinic, Laboratory Developed Test

CPT Code: 0075U

Short Descriptor: Cyp2d6 5' gene dup/mlt

Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 5' gene duplication/multiplication) (List separately in addition to code for primary procedure)

Laboratory: CYP2D6 5' gene duplication/multiplication targeted sequence analysis, Mayo Clinic, Laboratory Developed Test

CPT Code: 0076U

Short Descriptor: Cyp2d6 3' gene dup/mlt

Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 3' gene duplication/multiplication) (List separately in addition to code for primary procedure)

Laboratory: CYP2D6 3' gene duplication/multiplication targeted sequence analysis, Mayo Clinic, Laboratory Developed Test

CPT Code: 0077U

Short Descriptor: Ig paraprotein qual bld/ur

Long Descriptor: Immunoglobulin paraprotein (M-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype

Laboratory: M-Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry, Mayo Clinic, Laboratory Developed Test

CPT Code: 0078U

Short Descriptor: Pain mgt opi use gnotyp pnl

Long Descriptor: Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder

Laboratory: INFINITI® Neural Response Panel, PersonalizedX Labs, AutoGenomics Inc

New Codes Effective January 1, 2019

Proprietary Laboratory Analysis (PLAs)

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MACs shall only price PLA codes for laboratories within their jurisdiction.

New Codes

CPT Code: 0080U

Short Descriptor: ONC LNG 5 CLIN RSK FACTR ALG

Long Descriptor: Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy

Laboratory:BDX-XL2, Biodesix®, Inc

CPT Code: 0081U

Short Descriptor: ONC UVEAL MLNMA MRNA 15 GENE

Long Descriptor: Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis

Laboratory:DecisionDx®-UM, Castle Biosciences, Inc

CPT Code: 0082U

Short Descriptor: RX TEST DEF 90+ RX/SBSTS UR

Long Descriptor: Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service

Laboratory:NextGen Precision™ Testing, Precision Diagnostics LBN Precision Toxicology, LLC

CPT Code: 0083U

Short Descriptor: ONC RSPSE CHEMO CNTRST TOMOG

Long Descriptor: Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations

Laboratory:Onco4D™, Animated Dynamics, Inc

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
11076.1	A/B MAC Parts A and B contractors shall retrieve and implement the CY 2019 Clinical Laboratory Fee Schedule data file (filename: MU00.@BF12394.CLAB.V2019Q1) from the CMS mainframe on or after December 1, 2018.	X	X								
11076.1.1	A/B MAC Part B contractors shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., A/B MAC Part B name and number).		X								VDCs
11076.1.2	A/B MAC Part A contractors shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., A/B MAC Part A name and number).	X									VDCs
11076.2	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X	X								
11076.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis.		X								
11076.4	A/B MAC Part B contractors shall determine customary and prevailing charges by using data from July 1, 2017 through June 30, 2018, updated by the inflation-index update for year CY 2019 of 2.90 percent.		X								
11076.5	A/B MAC Part A contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients.	X									
11076.6	If there is a revision to the standard mileage rate for CY 2019, CMS shall issue a separate instruction on the clinical laboratory travel fees.										CMS

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
11076.7	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Rasheeda Johnson, 410-786-3434 or Rasheeda.Johnson1@cms.hhs.gov , Laura Ashbaugh, 4107861113 or laura.ashbaugh2@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0