

Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM12080 **Revised**

Related Change Request (CR) Number: 12080

Related CR Release Date: **January 20, 2021**

Effective Date: January 1, 2021

Related CR Transmittal Number: **R10575CP**

Implementation Date: January 4, 2021

PROVIDER TYPE AFFECTED

This MLN Matters Article is for clinical diagnostic laboratories that submit claims to Medicare Administrative Contractors (MACs) for laboratory services for Medicare beneficiaries.

PROVIDER ACTION NEEDED

Related CR 12080 provides instructions for the Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS), 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

The CY 2021 updates are as follows:

Advanced Diagnostic Laboratory Tests (ADLTs)

Refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests for further information on these tests.

See [MLN Matters Article MM12612](#) for more current information on this reporting period.

- **Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests — DELAYED**

Section 1834A of the Social Security Act (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. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The 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) was from January 1, 2019, through June 30, 2019.

- Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and Section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that are not ADLTs and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. In summary, the revisions are as follows:
 - The next data reporting period of January 1, 2022, through March 31, 2022, will be based on the original data collection period of January 1, 2019, through June 30, 2019.
 - After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2025, 2028, etc.).
 - The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through CY 2024. There is a 0.0 percent reduction for CY 2021, and payment may not be reduced by more than 15% for CYs 2022 through 2024.

COVID-19 Policy Updates

Payment for High Throughput Technologies

On October 15, 2020, CMS issued ruling CMS-2020-1-R2 which amends CMS Ruling 2020-1-R, which articulated CMS's policy concerning the designation and payment of certain CDLTs related to COVID-19 under the Medicare Part B CLFS.

CMS Ruling 2020-1-R defined certain highly sophisticated equipment called "high throughput technology." It also established a payment amount for molecular genomic CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and that are administered during the ongoing emergency period defined in paragraph (1)(B) of Section 1135(g) of the Act.

CMS Ruling 2020-2-R amends CMS Ruling 2020-1-R by modifying the payment amount established in that Ruling for such CDLT based on a re-evaluation of the resources necessary for the timely administration of these tests. The ruling:

- Establishes a revised payment amount for HCPCS codes U0003 and U0004 of \$75 per procedure (previously was \$100)
- Sets a new add-on payment amount of \$25 for HCPCS code U0005 which is to be used to indicate that the
 - corresponding CDLT (U0003 or U0004) that makes use of high throughput technology for the detection of SARS-CoV-2 or diagnosis of the virus that causes COVID-19 is completed within 2 calendar days of the specimen being collected, and
 - the laboratory completed a majority of these CDLTs (for all patients during the prior calendar month) in 2 calendar days or less from when the specimen was collected.

For more information on this policy update, please refer to <https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf>.

Clinical Laboratory Fee Schedule 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 2021 is 0.20%. Beginning January 1, 2021, 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 2021 national minimum payment amount is \$15.15 (This value reflects the CY 2020 national minimum payment with a 0.2% increase or \$15.12 times 1.0020). 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 2021 is 0.6% (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

You'll have Internet access to the CY 2021 CLFS data file at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>. It will be available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 22, 2020, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2019 codes and new CY 2021 CPT codes. Notice of the meeting was published in the **Federal Register** on May 4, 2020. Many attendees, including individuals representing laboratories, manufacturers, and medical societies made recommendations to CMS. We posted a summary of the meeting and the tentative payment determinations at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html. We accepted additional written comments from the public until October 21, 2020. We 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 2021 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.

We update the fees for clinical laboratory travel codes P9603 and P9604 on an annual basis. You may bill the clinical laboratory travel codes 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 2021, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2021 CLFS may also include 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. Code will be listed if applicable.

Mapping Information

CY 2021 CLFS Mapping Information

- New code 0141U is to be gapfilled
- New code 0142U is to be gapfilled
- New code 0151U is to be gapfilled
- New code 0202U is priced at the same rate as code 87633
- New code 0140U is to be gapfilled
- New code 0152U is to be gapfilled
- New code 0210U is priced at the same rate as code [0065U PLUS (0065U TIMES 0.03)]
- New code U0001 is to be gapfilled
- New code U0002 is to be gapfilled
- New code U0003 is to be gapfilled
- New code U0004 is to be gapfilled
- New code 87635 is to be gapfilled
- New code 86328 is to be gapfilled
- New code 86769 is to be gapfilled
- New code 0181U is priced at the same rate as code 81403
- New code 0182U is priced at the same rate as code 81405
- New code 0183U is priced at the same rate as code 81403
- New code 0184U is priced at the same rate as code 81403
- New code 0185U is priced at the same rate as code 81403
- New code 0186U is priced at the same rate as code 81403
- New code 0187U is priced at the same rate as code 81404
- New code 0188U is priced at the same rate as code 81404
- New code 0189U is priced at the same rate as code 81404
- New code 0190U is priced at the same rate as code 81404
- New code 0191U is priced at the same rate as code 81404
- New code 0192U is priced at the same rate as code 81404
- New code 0193U is priced at the same rate as code 81406
- New code 0194U is priced at the same rate as code 81403
- New code 0196U is priced at the same rate as code 81403
- New code 0197U is priced at the same rate as code 81403

- New code 0198U is priced at the same rate as code 81406
- New code 0199U is priced at the same rate as code 81404
- New code 0200U is priced at the same rate as code 81404
- New code 0201U is priced at the same rate as code 81403
- New code 0221U is to be gapfilled
- New code 0222U is to be gapfilled
- New code 0180U is to be gapfilled
- New code 0143U is to be gapfilled
- New code 0144U is to be gapfilled
- New code 0145U is priced at the same rate as code G0480
- New code 0146U is priced at the same rate as code G0480
- New code 0147U is priced at the same rate as code G0480
- New code 0148U is priced at the same rate as code G0480
- New code 0149U is priced at the same rate as code G0480
- New code 0150U is priced at the same rate as code G0480
- New code 80179 is priced at the same rate as code 80299
- New code 80151 is priced at the same rate as code 80299
- New code 80143 is priced at the same rate as code 80299
- New code 82077 is priced at the same rate as code 83520
- New code 80161 is priced at the same rate as code 80299
- New code 80167 is priced at the same rate as code 80299
- New code 80181 is priced at the same rate as code 80299
- New code 80189 is priced at the same rate as code 80187
- New code 80193 is priced at the same rate as code 80230
- New code 80204 is priced at the same rate as code 80230
- New code 80210 is priced at the same rate as code 80199
- New code 0219U is to be gapfilled
- New code 81513 is priced at the same rate as code 87631
- New code 81514 is priced at the same rate as code 87506
- New code 81546 is priced at the same rate as code 81545
- New code 0208U is to be gapfilled
- New code 0014M is priced at the same rate as code 0003M*0.35
- New code 0166U is priced at the same rate as code 0003M
- New code 0139U is to be gapfilled
- New code 0170U is priced at the same rate as code 0090U
- New code 81554 -NEW-This code was approved as an ADLT
- New code 0164U is to be gapfilled
- New code 0168U is priced at the same rate as code 81420
- New code 0174U is to be gapfilled
- New code 0015M is to be gapfilled
- New code 0016M is to be gapfilled
- New code 0163U is to be gapfilled
- Reconsidered code 81307 is priced at the same rate as code 81317

- Reconsidered code 0071U is priced at the same rate as code 81238
- Reconsidered code 0101U is to be gapfilled
- Reconsidered code 0102U is to be gapfilled
- Reconsidered code 0103U is to be gapfilled
- Reconsidered code 0129U is to be gapfilled
- New code 81168 is priced at the same rate as code 81315
- New code 81278 is priced at the same rate as code 81315
- New code 81191 is priced at the same rate as code 81315
- New code 81192 is priced at the same rate as code 81315
- New code 81193 is priced at the same rate as code 81315
- New code 0209U is to be gapfilled
- New code 81194 is priced at the same rate as code 81315 TIMES 2.5
- New code 0153U is to be gapfilled
- New code 0155U is priced at the same rate as code 81309
- New code 0177U is priced at the same rate as code 81309
- New code 0157U is to be gapfilled
- New code 0158U is to be gapfilled
- New code 0159U is to be gapfilled
- New code 0160U is to be gapfilled
- New code 0161U is to be gapfilled
- New code 0162U is to be gapfilled
- New code 81279 is priced at the same rate as code 81403
- New code 81338 is priced at the same rate as code 81402
- New code 81339 is priced at the same rate as code 81403
- New code 81347 is priced at the same rate as code 81120
- New code 81348 is priced at the same rate as code 81233
- New code 81357 is priced at the same rate as code 81120
- New code 81360 is priced at the same rate as code 81120
- New code 0171U is to be gapfilled
- New code 81351 is priced at the same rate as code 81298
- New code 81353 is priced at the same rate as code 81299
- New code 81352 is priced at the same rate as code 81334
- New code 0154U is priced at the same rate as code 81309 PLUS 81315
- New code 0156U is to be gapfilled
- New code 0179U is to be gapfilled
- New code 0195U is priced at the same rate as code 81215
- New code 0169U is priced at the same rate as code 0034U
- New code 0165U is to be gapfilled
- New code 0167U is priced at the same rate as code 84703
- New code 0178U is to be gapfilled
- New code 81419 is priced at the same rate as code 81443
- New code 0173U is to be gapfilled
- New code 0175U is to be gapfilled

- New code 0203U is priced at the same rate as code 0011M
- New code 0204U is priced at the same rate as code 81455
- New code 0205U is priced at the same rate as code 81330
- New code 0211U is priced at the same rate as code 0019U PLUS 0036U
- New code 0212U is to be gapfilled
- New code 0213U is to be gapfilled
- New code 0214U is to be gapfilled
- New code 0215U is to be gapfilled
- New code 0216U is to be gapfilled
- New code 0217U is to be gapfilled
- New code 0218U is priced at the same rate as code 81408 PLUS 81161
- New code 0176U is priced at the same rate as code 86828
- New code 0206U is to be gapfilled
- New code 0207U is to be gapfilled
- New code 0220U is to be gapfilled
- New code 82681 is priced at the same rate as code 82670
- New Code U0002QW is priced at the same rate as code U0002
- New Code 87635QW is priced at the same rate as code 87635
- New Code 87426QW is priced at the same rate as code 87426
- Existing code 0006U is deleted
- Existing code 0124U is deleted
- Existing code 0125U is deleted
- Existing code 0126U is deleted
- Existing code 0127U is deleted
- Existing code 0128U is deleted
- Existing code 87450 is deleted

Laboratory Costs Subject to Reasonable Charge Payment in CY 2020

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 2021 is **0.60%**.

Manual instructions for determining the reasonable charge payment are in Chapter 23, Sections 80 through 80.8 of the Medicare Claims Processing Manual at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf>. 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. Chapter 8, Section 60.3 of the Medicare Claims Processing Manual, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf>, 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).

Laboratory Costs Subject to Reasonable Charge Payment in CY 2021

Code Category	Codes
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 89290 89291 89335 89337 89342 89343 89344 89346 89352 89353 89354 89356

New Codes Effective October 6, 2020

The listed new codes are on the national HCPCS file with an effective date of October 6, 2020, and do not need to be manually added to the HCPCS files by the MACs. These new codes are contractor-priced (where applicable) until they are nationally priced and undergoes the CLFS annual payment determination process in accordance with the Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- Code: 87636

- Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
- Short Descriptor: SARSCOV2 & INF A&B AMP PRB
- Type of Service (TOS): 5
- Code: 87637
 - Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
 - Short Descriptor: SARSCOV2&INF A&B&RSV AMP PRB
 - TOS: 5
- Code: 87811
 - Long Descriptor: Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
 - Short Descriptor: SARS-COV-2 COVID19 W/OPTIC
 - TOS: 5

Proprietary Laboratory Analysis (PLAs)

The listed new codes have been added to the national HCPCS file with an effective date of October 6, 2020, and do not need to be manually added to the HCPCS files 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 2021 as they were received after the 2020 public meeting. MACs only price PLA codes for laboratories within their jurisdiction.

- Code: 0240U
 - Long Descriptor: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
 - Short Descriptor: NFCT DS VIR RESP RNA 3 TRGT
 - Laboratory Name: Xpert® Xpress SARS-CoV-2/Flu/RSV (SARS-CoV-2 & Flu targets only), Cepheid
 - TOS: 5
- Code: 0241U

- Long Descriptor: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
- Short Descriptor: NFCT DS VIR RESP RNA 4 TRGT
- Laboratory Name: Xpert® Xpress SARS-CoV-2/Flu/RSV (all targets), Cepheid
- TOS: 5

New Codes Effective November 10, 2020

The listed new code will be added to the national HCPCS file with an effective date of November 10, 2020, and does not need to be manually added to the HCPCS files by the MACs. However, the new code is contractor-priced (where applicable) until it is nationally priced and undergoes the CLFS annual payment determination process in accordance with the Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- Code: 87428
 - Long Descriptor: Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARSCoV-2 [COVID-19]) and influenza virus types A and B
 - Short Descriptor: SARSCOV & INF VIR A&B AG IA
 - TOS: 5

New Codes Effective January 1, 2021

Per the above discussion in the COVID-19 Policy Updates section, Payment for High Throughput Technologies, we added the listed new code to the national HCPCS file with an effective date of January 1, 2021, and doesn't need to be manually added to the HCPCS files by the MACs. Such tests, as identified by U0005, in accordance with CMS Ruling CMS-2020-02-R, shall be paid at the rate of \$25.

This new code is:

- Code: U0005
 - Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (List separately in addition to either HCPCS code U0003 or U0004) as described by CMS-2020-01-R2.
 - Short Descriptor: Infec agen detec ampli probe

- Type of Service: 5

Proprietary Laboratory Analysis (PLAs)

New Codes Effective January 1, 2021

PLAs: The following new codes have been added to the national HCPCS file with an effective date of January 1, 2021. 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 of 2021, as they were received after the 2020 public meeting. MACs will only price PLA codes for laboratories within their jurisdiction.

- CPT Code: 0227U
 - Long Descriptor: Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation
 - Short Descriptor: RX ASY PRSMV 30+RX/METABLT
 - Laboratory: Comprehensive Screen, Aspenti Health
- CPT Code: 0228U
 - Long Descriptor: Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer
 - Short Descriptor: ONC PRST8 MA MOLEC PRFL ALG
 - Laboratory: PanGIA Prostate, Genetics Institute of America, Entopsis, LLC
- CPT Code: 0229U
 - Long Descriptor: BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis
 - Short Descriptor: BCAT1 PROMOTER MTHYLTN ALYS
 - Laboratory: Colvera®, Clinical Genomics Pathology Inc
- CPT Code: 0230U
 - Long Descriptor: AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
 - Short Descriptor: AR FULL SEQUENCE ANALYSIS
 - Laboratory: Genomic Unity® AR Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0231U
 - Long Descriptor: CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in

- exonic and intronic regions, deletions, duplications, Short Tandem Repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions
- Short Descriptor: CACNA1A FULL GENE ANALYSIS
- Laboratory: Genomic Unity® CACNA1A Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0232U
 - Long Descriptor: CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, Short Tandem Repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
 - Short Descriptor: CSTB FULL GENE ANALYSIS
 - Laboratory: Genomic Unity® CSTB Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0233U
 - Long Descriptor: FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
 - Short Descriptor: FXN GENE ANALYSIS
 - Laboratory: Genomic Unity® FXN Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0234U
 - Long Descriptor: MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
 - Short Descriptor: MECP2 FULL GENE ANALYSIS
 - Laboratory: Genomic Unity® MECP2 Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0235U
 - Long Descriptor: PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
 - Short Descriptor: PTEN FULL GENE ANALYSIS
 - Laboratory: Genomic Unity® PTEN Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0236U
 - Long Descriptor: SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions

- Short Descriptor: SMN1&SMN2 FULL GENE ANALYSIS
- Laboratory: Analysis, Variantyx Inc, Variantyx Inc

- CPT Code: 0237U
 - Long Descriptor: Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
 - Short Descriptor: CAR ION CHNLPHTY GEN SEQ PNL
 - Laboratory: Genomic Unity® Cardiac Ion Channelopathies Analysis, Variantyx Inc, Variantyx Inc

- CPT Code: 0238U
 - Long Descriptor: Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
 - Short Descriptor: ONC LNCH SYN GEN DNA SEQ ALY
 - Laboratory: Genomic Unity® Lynch Syndrome Analysis, Variantyx Inc, Variantyx Inc

- CPT Code: 0239U
 - Long Descriptor: Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations
 - Short Descriptor: TRGT GEN SEQ ALYS PNL 311+
 - Laboratory: FoundationOne® Liquid CDx, FOUNDATION MEDICINE, INC, FOUNDATION MEDICINE, INC

ADDITIONAL INFORMATION

The official instruction, CR 12080, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10575CP.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
March 21, 2022	We revised this Article to add a link to Article MM12612 , which has current information on the Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests. All other information is the same.
January 20, 2021	We revised this article to reflect a revised CR 12080, that CMS issued on January 20, 2021. In the CR, CMS changed the payment determination for code 0177U in the crosswalk from 81310 to 81309. We made that same change as shown on page 6. Also, we changed the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
December 18, 2020	Initial article released.

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