



Calendar Year (CY) 2020 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM11598 **Revised**

Related Change Request (CR) Number: 11598

Related CR Release Date: **January 22, 2020**

Effective Date: January 1, 2020

Related CR Transmittal Number: **R4498CP**

Implementation Date: January 6, 2020

Note: We revised this article on January 23, 2020, due to an updated CR 11598 that changed the policy section. Per the CR, the article notes that “Next CLFS Data Reporting Period — DELAYED to January 2021 (page 1).” That is also noted on page 3. The article also has policy changes on page 2. The CR release date, transmittal number and link to the transmittal also changed. All other information remains the same.

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

CR 11598 provides instructions for the Calendar Year (CY) 2020 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 2020 updates are as follows:

Next CLFS Data Reporting Period — DELAYED to January 2021

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. The Centers for Medicare & Medicaid Services (CMS) published the CLFS final rule Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F) 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 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.

- **For Clinical Diagnostic Laboratory Tests (CDLTs) that are not Advanced Diagnostic Laboratory Tests (ADLTs), the data reporting is delayed by one year.** CDLT data that was supposed to be reported between January 1, 2020 and March 31, 2020, must now be reported between **January 1, 2021, and March 31, 2021.** Labs must report data from the original data collection period of January 1, 2019, through June 30, 2019. Data reporting for these tests will then resume on a three-year cycle, beginning in 2024. (Section 105(a)(1) of the Further Consolidated Appropriations Act of 2020 (FCAA)).
- In addition, the statutory phase-in provisions are updated. For 2020, the rates for CDLTs that are not ADLTs or new CLDTs may not be reduced by more than 10 percent of the rates for 2019. There will be a 15 percent reduction cap for each of 2021, 2022, and 2023. (Section 105(a)(2) of FCAA).

Reminder: 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 were excluded from total Medicare revenues (the denominator of the majority of Medicare revenues threshold).
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. An 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 CFR 493.2](#))
2. The laboratory bills Medicare under its own National Provider Identifier (NPI) or
 - a. For hospital outreach laboratories -- bills Medicare Part B on the Form CMS 1450 under TOB.
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. **As a reminder, 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 CLFS data collection period was 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, were required to determine applicable laboratory status from their final paid Medicare claims received during the next data collection period. Hospital outreach laboratories that met 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, 2021, through March 31, 2021**. Additional sub regulatory guidance will be made available on the CLFS website under the PAMA regulations tab at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html>.

Advanced Diagnostic Laboratory Tests (ADLTs) Effective January 1, 2020

1. The ADLT DecisionDx-Uveal Melanoma owned and furnished by Castle Bioscience was assigned Proprietary Laboratory Analyses (PLA) code 0081U effective January 1, 2019. This code is being deleted effective December 31, 2019 and replaced by CPT code 81552, effective January 1, 2020.
 - CPT Code: 81552
 - 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), utilizing fine needle aspirate or formalin-fixed paraffin embedded tissue, algorithm reported as risk of metastasis
2. Existing code 81538 is an ADLT and is priced at its median private payer rate.
3. For additional information regarding other ADLTs, see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations#ADLT_tests.

Update to Fees

Based on Section 1833(h)(2)(A)(i) of the Act, available at https://www.ssa.gov/OP_Home/ssact/title18/1833.htm, the annual update to the local clinical laboratory fees for **CY 2020** is 0.90 percent. Beginning **January 1, 2020**, 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 2020** national minimum payment amount is **\$15.12** (This value reflects the **CY 2019** national minimum payment with a **0.9 percent** increase or **\$14.99 times 1.0090**).

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 2020 is 1.6 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

Internet access to the CY 2020 CLFS data file will be available after December 1, 2019, 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 24, 2019, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2019 codes and new CY 2020 CPT codes. Notice of the meeting was published in the Federal Register on April 1, 2019. 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 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 27, 2019. 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 2020 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 2020, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2020 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**Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Mapping Information**

- New code 0064U is priced at the same rate as code 86780 PLUS code 86318
- New code 0065U is priced at the same rate as code 86318
- New code 0068U is priced at the same rate as code 87631
- New code 0086U is to be gapfilled.
- New code 0096U is priced at the same rate as code 87624
- New code 0097U is to be gapfilled
- New code 0098U is to be gapfilled
- New code 0099U is to be gapfilled
- New code 0100U is to be gapfilled
- New code 87563 is priced at the same rate as code 87491
- New code 0109U is priced at the same rate as code 87631
- New code 0115U is to be gapfilled
- New code 0084U is priced at the same rate as code 0001U
- New code 0121U is to be gapfilled
- New code 0122U is to be gapfilled
- New code 0123U is to be gapfilled
- New code 0062U is to be gapfilled
- New code 0063U is to be gapfilled
- New code 0066U is priced at the same rate as code 87808
- New code 0067U is to be gapfilled
- New code 0077U is to be gapfilled
- New code 0082U is priced at the same rate as code 0006U
- New code 0092U is to be gapfilled
- New code 0093U is priced at the same rate as code 80307
- New code 0095U is to be gapfilled
- New code 80145 is priced at the same rate as code 80155
- New code 80230 is priced at the same rate as code 80155
- New code 80235 is priced at the same rate as code 80199
- New code 80187 is priced at the same rate as code 80199
- New code 80280 is priced at the same rate as code 80155
- New code 80285 is priced at the same rate as code 80199
- New code 0105U is priced at the same rate as code 0003U
- New code 0106U is to be gapfilled
- New code 0107U is priced at the same rate as code 87803
- New code 0108U is to be gapfilled
- New code 0110U is priced at the same rate as code 80199
- New code 0116U is priced at the same rate as code 0006U
- New code 0117U is to be gapfilled
- New code 0119U is to be gapfilled
- New code 0124U is priced at the same rate as code 81510
- New code 0125U is priced at the same rate as code 81512

- New code 0126U is priced at the same rate as code 81512
- New code 0127U is priced at the same rate as code 81510
- New code 0128U is priced at the same rate as code 81510
- New code 81307 is priced at the same rate as code 81406
- New code 81308 is priced at the same rate as code 81405
- New code 81309 is priced at the same rate as code 81404
- New code 0069U is priced at the same rate as code 0005U TIMES 0.50
- New code 0078U is priced at the same rate as code 81226
- New code 0089U is priced at the same rate as code 0005U
- New code 81522 is priced at the same rate as code 81518
- New code 0111U is priced at the same rate as code 81275 PLUS 81276 PLUS 81311
- New code 0112U is to be gapfilled
- New code 0113U is priced at the same rate as code 0005U
- New code 0114U is to be gapfilled
- New code 0120U is priced at the same rate as code 81520
- New code 0129U is priced at the same rate as code 81432 PLUS 81433
- New code 0130U is priced at the same rate as code 81435
- New code 0131U is to be gapfilled
- New code 0132U is to be gapfilled
- New code 0133U is to be gapfilled
- New code 0134U is to be gapfilled
- New code 0135U is to be gapfilled
- New code 0136U is to be gapfilled
- New code 0137U is to be gapfilled
- New code 0138U is to be gapfilled
- New code 0094U is to be gapfilled
- New code 0101U is priced at the same rate as code 81435 PLUS 81436
- New code 0102U is priced at the same rate as code 81432 PLUS 81433
- New code 0103U is priced at the same rate as code 81432 PLUS 81433
- Reconsidered code 81163 is priced at the same rate as code 81406 PLUS 81216
- Reconsidered code 81165 is priced at the same rate as code 81406
- Reconsidered code 0046U is to be gapfilled
- Reconsidered code 0049U is to be gapfilled
- New code 0070U is priced at the same rate as code 81226 TIMES 1.5
- New code 0071U is priced at the same rate as code 81405
- New code 0072U is priced at the same rate as code 81226
- New code 0073U is priced at the same rate as code 81226
- New code 0074U is priced at the same rate as code 81226
- New code 0075U is priced at the same rate as code 81226
- New code 0076U is priced at the same rate as code 81226
- New code 0083U is to be gapfilled
- New code 0087U is to be gapfilled
- New code 0088U is to be gapfilled

- New code 0118U is to be gapfilled
- New code 81277 is priced at the same rate as code 81229
- Existing code 0009M is to be 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 2020 is **1.60 percent**.

Manual instructions for determining the reasonable charge payment are available 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 table 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 2020

Code Category	Codes
Blood Products	<p>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</p> <p>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:</p> <p>P9010 P9016 P9021 P9022 P9038 P9039 P9040 P9051 P9054 P9056 P9057 P9058</p> <p>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.</p>
Transfusion Medicine	<p>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</p>
Reproductive Medicine Procedures	<p>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</p>

New Codes Effective January 1, 2020

PLAs

The following new codes have been added to the national HCPCS file with an effective date of January 1, 2020. 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 2020, as they were received after the 2019 public meeting. MACs will only price PLA codes for laboratories within their jurisdiction.

- CPT Code: 0139U
 - Short Descriptor: NEURO AUSTM MEAS 6 C METABLT
 - Long Descriptor: Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, α -ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)

- Laboratory: NPDX ASD EnergyMetabolism, Stemina Biomarker Discovery, Inc., Stemina Biomarker Discovery, Inc.
- CPT Code:0140U
 - Short Descriptor: NFCT DS FUNGI DNA 15 TRGT
 - Long Descriptor: Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected
 - Laboratory: ePlex® BCID Fungal Pathogens Panel, GenMark Diagnostics, Inc., GenMark Diagnostics, Inc.
- CPT Code:0141U
 - Short Descriptor: NFCT DS BACT&FNG GRAM POS
 - Long Descriptor: Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected
 - Laboratory: ePlex® BCID GramPositive Panel, GenMark Diagnostics, Inc., GenMark Diagnostics, Inc.
- CPT Code:0142U
 - Short Descriptor: NFCT DS BACT&FNG GRAM NEG
 - Long Descriptor: Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected
 - Laboratory: ePlex® BCID GramNegative Panel, GenMark Diagnostics, Inc., GenMark Diagnostics, Inc.
- CPT Code: 0143U
 - Short Descriptor: DRUG ASSAY 120+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: CareViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC
- CPT Code: 0144U
 - Short Descriptor: DRUG ASSAY 160+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: CareViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC

- CPT Code: 0145U
 - Short Descriptor: DRUG ASSAY 65+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: PainViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC
- CPT Code: 0146U
 - Short Descriptor: DRUG ASSAY 80+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: PainViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC
- CPT Code: 0147U
 - Short Descriptor: DRUG ASSAY 85+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: RiskViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC
- CPT Code: 0148U
 - Short Descriptor: DRUG ASSAY 100+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: RiskViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC
- CPT Code: 0149U
 - Short Descriptor: DRUG ASSAY 60+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: PsychViewRx, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC

- CPT Code: 0150U
 - Short Descriptor: DRUG ASSAY 120+ RX/METABLT
 - Long Descriptor: Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
 - Laboratory: PsychViewRx Plus, Newstar Medical Laboratories, LLC, Newstar Medical Laboratories, LLC
- CPT Code: 0151U
 - Short Descriptor: NFCT BCT/VIR RESP NFCTJ 33
 - Long Descriptor: Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 targets, real-time semi-quantitative PCR, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes with limited semi-quantitative result
 - Laboratory: BioFire® FilmArray® Pneumonia Panel, BioFire® Diagnostics, BioFire® Diagnostics
- CPT Code: 0152U
 - Short Descriptor: NFCT BCT FNG PRST DNA >1000
 - Long Descriptor: Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens
 - Laboratory: Karius® Test, Karius Inc, Karius Inc
- CPT Code: 0153U
 - Short Descriptor: ONC BREAST MRNA 101 GENES
 - Long Descriptor: Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement
 - Laboratory: Insight TNBCtype™, Insight Molecular Labs
- CPT Code: 0154U
 - Short Descriptor: FGFR3 GENE ANALYSIS
 - Long Descriptor: FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3)
 - Laboratory: theascreen® FGFR RGQ RT-PCR Kit, QIAGEN, QIAGEN GmbH
- CPT Code: 0155U
 - Short Descriptor: PIK3CA GENE ANALYSIS
 - Long Descriptor: PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y)
 - Laboratory: theascreen PIK3CA RGQ PCR Kit, QIAGEN, QIAGEN GmbH

- CPT Code: 0156U
 - Short Descriptor: COPY NUMBER SEQUENCE ALYS
 - Long Descriptor: Copy number (eg, intellectual disability, dysmorphology), sequence analysis
 - Laboratory: SMASH™, New York Genome Center, Marvel Genomics™
- CPT Code: 0157U
 - Short Descriptor: APC MRNA SEQ ALYS
 - Long Descriptor: APC (APC regulator of WNT signaling pathway) (eg, familial adenomatosis polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure)
*(Use 0157U in conjunction with 81201)
 - Laboratory: CustomNext + RNA: APC, Ambry Genetics®, Ambry Genetics®
- CPT Code: 0158U
 - Short Descriptor: MLH1 MRNA SEQ ALYS
 - Long Descriptor: MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
*(Use 0158U in conjunction with 81292)
 - Laboratory: CustomNext + RNA: MLH1, Ambry Genetics®, Ambry Genetics®
- CPT Code: 0159U
 - Short Descriptor: MLH1 MRNA SEQ ALYS
 - Long Descriptor: MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
*(Use 0159U in conjunction with 81295)
 - Laboratory: CustomNext + RNA: MSH2, Ambry Genetics®, Ambry Genetics®
- CPT Code: 0160U
 - Short Descriptor: MSH6 MRNA SEQ ALYS
 - Long Descriptor: MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
*(Use 0160U in conjunction with 81298)
 - Laboratory: CustomNext + RNA:MSH6, AmbryGenetics®, Ambry Genetics®
- CPT Code: 0161U
 - Short Descriptor: PMS2 MRNA SEQ ALYS
 - Long Descriptor: PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
*(Use 0161U in conjunction with 81317)
 - Laboratory: CustomNext + RNA:PMS2, Ambry Genetics®, Ambry Genetics®
- CPT Code: 0162U
 - Short Descriptor: HERED COLON CA TRGT MRNA PNL
 - Long Descriptor: Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)

- *(Use 0162U in conjunction with 81292, 81295, 81298, 81317, 81435)
- Laboratory: CustomNext + RNA:Lynch (MLH1, MSH2,MSH6, PMS2), AmbryGenetics®, AmbryGenetics®

ADDITIONAL INFORMATION

The official instruction, CR11598, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r4498CP.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
January 23, 2020	We revised this article due to an updated CR that changed the policy section. Per the CR, the article notes that “Next CLFS Data Reporting Period — DELAYED to January 2021 (page 1).” That is also noted on page 3. The article also has policy changes on page 2. The CR release date, transmittal number and link to the transmittal also changed. All other information remains the same.
January 14, 2020	We revised this article to add a link to a related article SE19006 . SE19006 states that for CDLTs that are not ADLTs, the data reporting is delayed by one year and must now be reported between January 1, 2021, and March 31, 2021 (previously January 1, 2020, through March 31, 2020). The article also added the “CLFS Data Reporting Delayed” Section on page 24 to summarize the changes.
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