mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM11280 | Related Change Request (CR) Number: 11280
Related CR Release Date: June 28, 2019 | Effective Date: July 1, 2019
Related CR Transmittal Number: R4326CP | Implementation Date: July 1, 2019

Note: We revised this article on July 3, 2019, to reflect a revised CR that CMS posted on June 28. In the article, we added a section on page 5 regarding Advanced Diagnostic Laboratory Tests. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters® Article is for physicians, other providers, and suppliers submitting clinical laboratory claims to Medicare Administrative Contractors (MACs)) for services to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11280 informs MACS about the changes in the July 2019 quarterly update to the Clinical Laboratory Fee Schedule (CLFS). Make sure that your billing staffs are aware of these changes.

BACKGROUND

Effective January 1, 2018, Medicare bases CLFS rates on weighted median private payor rates as the Protecting Access to Medicare Act (PAMA) of 2014 requires. For more details, visit PAMA Regulations at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

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

Access to Data File

The quarterly CLFS data file will be available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, may want to retrieve the quarterly CLFS. It will be available in multiple formats: Excel, text, and comma delimited.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

Pricing Information

The CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). Section 1833(h)(4)(B) of the Social Security Act provides for establishing these fees.

New Codes Effective July 1, 2019

Proprietary Laboratory Analysis (PLAs)

The following new codes may need to be manually added to the HCPCS file by the MACs with an effective date of July 1, 2019. These new codes are also contractor-priced until they appear on the January 1, 2020 CLFS as applicable.

Note: MACs will only price PLA codes for laboratories within their jurisdiction.

- CPT Code: 0084U
  - Long Descriptor: Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens
  - Short descriptor: RBC DNA GNOTYP 10 BLD GROUPS
  - Laboratory: BLOODchip®ID CORE XT™, Grifols Diagnostic Solutions Inc
  - TOS: 5
- CPT Code: 0085U
  - Long Descriptor: Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)
  - Short Descriptor: CDTB&VINCULIN IGG ANTB IA
  - Laboratory: Accelerate PhenoTest™ BC kit, Accelerate Diagnostics, Inc
  - TOS: 5
- CPT Code: 0086U
  - Long Descriptor: Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility
  - Short Descriptor: NFCT DS BACT&FNG ORG ID 6+
  - Laboratory: Accelerate PhenoTest™ BC kit, Accelerate Diagnostics, Inc
  - TOS: 5
- CPT Code: 0087U
  - Long Descriptor: Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score
  - Short Descriptor: CRD HRT TRNSPL MRNA 1283 GEN
  - Laboratory: Molecular Microscope® MMDx—Heart, Kashi Clinical Laboratories
  - TOS: 5
- CPT Code: 0088U

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

  - Long Descriptor: Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection
  - Short Descriptor: TRNSPLJ KDN ALGRFT REJ 1494
  - Laboratory: Molecular Microscope® MMDx—Kidney, Kashi Clinical Laboratories
  - TOS: 5

- CPT Code: 0089U
  - Long Descriptor: Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)
  - Short Descriptor: ONC MLNMA PRAME & LINC00518
  - Laboratory: Pigmented Lesion Assay (PLA), DermTech
  - TOS: 5
- CPT Code: 0090U
  - Long Descriptor: Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant)
  - Short Descriptor: ONC CUTAN MLNMA MRNA 23 GENE
  - Laboratory: myPath® Melanoma, Myriad Genetic Laboratories
  - TOS: 5
- CPT Code: 0092U
  - Long Descriptor: Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy
  - Short Descriptor: ONC LNG 3 PRTN BMRK PLSM ALG
  - Laboratory: REVEAL Lung Nodule Characterization, MagArray, Inc
  - TOS: 5
- CPT Code: 0093U
  - Long Descriptor: Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected
  - Short Descriptor: RX MNTR 65 COM DRUGS URINE
  - Laboratory: ComplyRX, Claro Labs
  - TOS: 5
- CPT Code: 0094U
  - Long Descriptor: Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis
  - Short Descriptor: GENOME RAPID SEQUENCE ALYS
  - Laboratory: RCIGM Rapid Whole Genome Sequencing, Rady Children's Institute for Genomic Medicine (RCIGM)
  - TOS: 5

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

- CPT Code: 0095U
  - Long Descriptor: Inflammation (eosinophilic esophagitis), ELISA analysis of eotaxin-3 (CCL26 [C-C motif chemokine ligand 26]) and major basic protein (PRG2 [proteoglycan 2, pro eosinophil major basic protein]), specimen obtained by swallowed nylon string, algorithm reported as predictive probability index for active eosinophilic esophagitis
  - Short Descriptor: INFLM EE ELISA ALYS ALG
  - Laboratory: Esophageal String Test™ (EST), Cambridge Biomedical, Inc
  - TOS: 5
- CPT Code: 0096U
  - Long Descriptor: Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine
  - Short Descriptor: HPV HI RISK TYPES MALE URINE
  - Laboratory: HPV, High-Risk, Male Urine, Molecular Testing Labs
  - TOS: 5
- CPT Code: 0097U
  - Long Descriptor: Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter [C. jejuni/C. coli/C. upsaliensis], Clostridium difficile [C. difficile] toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio [V. parahaemolyticus/V. vulnificus/V. cholerae], including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative Escherichia coli [EAEC], Enteropathogenic Escherichia coli [EPEC], Enterotoxigenic Escherichia coli [ETEC] lt/st, Shiga-like toxin-producing Escherichia coli [STEC] stx1/stx2 [including specific identification of the E. coli O157 serogroup within STEC], Shigella/Enteroinvasive Escherichia coli [EIEC], Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia [also known as G. intestinalis and G. duodenalis], adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, sapovirus [Genogroups I, II, IV, and V])
  - Short Descriptor: GI PATHOGEN 22 TARGETS
  - Laboratory: BioFire® FilmArray® Gastrointestinal (GI) Panel, BioFire® Diagnostics
  - TOS: 5
- CPT Code: 0098U
  - Long Descriptor: Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae);
  - Short Descriptor: RESPIR PATHOGEN 14 TARGETS
  - Laboratory: BioFire® FilmArray® Respiratory Panel (RP) EZ, BioFire® Diagnostics
  - TOS: 5

- CPT Code: 0099U
  - Long Descriptor: Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)
  - Short Descriptor: RESPIR PATHOGEN 20 TARGETS
  - Laboratory: BioFire® FilmArray® Respiratory Panel (RP), BioFire® Diagnostics
  - TOS: 5
- CPT Code: 0100U
  - Long Descriptor: Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)
  - Short Descriptor: RESPIR PATHOGEN 20 TARGETS;
  - Laboratory: BioFire® FilmArray® Respiratory Panel 2 (RP2), BioFire® Diagnostics
  - TOS: 5
- CPT Code: 0101U;
  - Long Descriptor: Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])
  - Short Descriptor: HERED COLON CA DO 15 GENES
  - Laboratory: ColoNext®, Ambry Genetics®, Ambry Genetics®
  - TOS: 5
- CPT Code: 0102U
  - Long Descriptor: Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])
  - Short Descriptor: HERED BRST CA RLTD DO 17 GEN
  - Laboratory: BreastNext®, Ambry Genetics®, Ambry Genetics®
  - TOS: 5

- CPT Code: 0103
  - Long Descriptor: Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])
  - Short Descriptor: HERED OVA CA PNL 24 GENES
  - Laboratory: OvaNext®, Ambry Genetics®, Ambry Genetics®
  - TOS: 5
- CPT Code: 0104U
  - Long Descriptor: Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])
  - Short Descriptor: HERED PAN CA PNL 32 GENES
  - Laboratory: CancerNext®, Ambry Genetics®, Ambry Genetics®
  - TOS: 5

Deleted Codes Effective July 1, 2019

- Existing code 0057U is being deleted.

Advanced Diagnostic Laboratory Tests (ADLTs) Effective July 1, 2019

CMS approved three ADLTs. For additional information regarding these tests, please refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests.

ADDITIONAL INFORMATION

The official instruction, CR11280, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4326CP.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
July 3, 2019	We revised the article to reflect a revised CR that CMS posted on June 28. In the article, we added a section on page 6 regarding Advanced Diagnostic Laboratory Tests. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
May 3, 2019	Initial article released.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

Disclaimer: This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2018 American Medical Association. All rights reserved.

Copyright © 2013-2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com

The American Hospital Association (the “AHA”) has not reviewed, and is not responsible for, the completeness or accuracy of any information contained in this material, nor was the AHA or any of its affiliates, involved in the preparation of this material, or the analysis of information provided in the material. The views and/or positions presented in the material do not necessarily represent the views of the AHA. CMS and its products and services are not endorsed by the AHA or any of its affiliates.