Centers for Medicare and Medicaid Services (CMS)

Clinical Laboratory Fee Schedule (CLFS) Annual Laboratory Public Meeting

June 22, 2020

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Clinical Laboratory Fee Schedule Recommendations

Reconsideration HCPCS, Level I (CPT) test code:
Molecular Pathology
81307 *PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence*

Public Comment	Rationale
81317 x1 ($676.50)	Comparable resources are required to complete the full gene sequence analysis of *PMS2* (postmeiotic segregation increased 2 [S.cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome).

Clinical Laboratory Fee Schedule Recommendations

HCPCS, Level I (CPT) test code:

Microbiology

87635 *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*

Public Comment	Rationale
87502 x1 ($95.80)	Comparable resources are required for the influenza virus infectious agent detection using an amplified probe technique. The current CMS MAC payment amount for CPT code 87635 should be updated to adequately reflect the clinical labor, equipment, reagents and supplies necessary to perform this COVID-19 diagnostic assay in the typical laboratory setting.

Clinical Laboratory Fee Schedule Recommendations

HCPCS, Level I (CPT) test code:

Immunology

86328 *Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])*

Public Comment	Rationale
86794 x2.5 x1 ($42.12)	Comparable resources are used.

Clinical Laboratory Fee Schedule Recommendations

HCPCS, Level I (CPT) test code:
Immunology
86769 *Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])*

Public Comment	Rationale
86794 x2.5 x1 ($42.12)	Comparable resources are used.

Clinical Laboratory Fee Schedule Recommendations

HCPCS, Level I (CPT) test code:

Genomic Sequencing Procedures

81XX6 *Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2*

Public Comment	Rationale
81413 X2 ($1,169.80)	Comparable resources are required to complete the Cardiac ion channelopathies genomic sequence analysis panel.

Clinical Laboratory Fee Schedule Recommendations

HCPCS, Level I (CPT) test codes:

Molecular Pathology

8X000 NTRK1 (neurotrophic receptor tyrosine kinase 1) translocation analysis
8X001 NTRK2 (neurotrophic receptor tyrosine kinase 2) translocation analysis
8X002 NTRK3 (neurotrophic receptor tyrosine kinase 3) translocation analysis

Public Comment	Rationale
81315 x1 ($207.31)	Similar resources are used in the *PML/RARalpha, (t(15;17))* translocation analysis for common breakpoints.

Clinical Laboratory Fee Schedule Recommendations

A complete list of CAP CLFS CY2021 recommendations has been submitted to the CMS in a supplemental spreadsheet.

Thank you!