ACLA Payment Recommendations for CY2021 Codes

Clinical Lab Fee Schedule Public Meeting
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ACLA
American Clinical Laboratory Association

ACLA General Recommendations on the Molecular Pathology Codes

American Clinical Laboratory Association

- For those tests that ACLA is providing oral comment, we have offered a crosswalk to an existing test with similar materials, methods, purposes and other pertinent technical information related to the number of exons, amount of DNA interrogated, size of the gene and other unique structural content relative for the specific gene analysis (e.g., a smaller gene may require less resources than a more complex or larger gene).

ACLA Recommendations on Reconsideration Codes

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
Reconsideration					
81307	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence	81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	ACLA recommends that CMS instead crosswalk CPT code 81307 to 81317 (PMS2, postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis. PALB2 has 14 exons, 1186 amino acids; PMS2 has 14 exons, 863 amino acids. This analyte-specific crosswalk represents similar work and resources. The Tier 1 CPT code 81317 is a more appropriate crosswalk for code 81307, as the work and resources align with the number of exons studied in the PALB2 gene analysis, full gene sequence.	$676.50
0071U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, full gene sequence	81238	F9 (coagulation factor IX) (eg, hemophilia B), full gene sequence	We maintain that this crosswalk, F9 gene analysis represents the code most similar in methodology and resources as the CYP2D6 full gene sequence analysis. Current crosswalk to 81405 ($301.45) undervalues full gene sequence analysis as the variant sequences under codes 0072U-0076U have all been priced at $450.91. All other code families of full gene sequence and variants have been priced with the full gene sequence higher than the variants, which is reasonable with the resource differences between full gene sequencing and variant gene sequencing.	$600.00

ACLA Recommendations on Reconsideration Codes (cont'd)

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
0101U	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])	Gap fill		Appealed 2020 crosswalk recommendation. For 2021, requesting Gap fill for component codes plus additional procedures for non-GSP molecular analysis for comparable resources and work for special variant of unknown significance analytics.	
0102U	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])	Gap fill		Appealed 2020 crosswalk recommendation. For 2021, requesting Gap fill for component codes plus additional procedures for non-GSP molecular analysis for comparable resources and work for special variant of unknown significance analytics.	
0103U	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])	Gap fill		Appealed 2020 crosswalk recommendation. For 2021, requesting Gap fill for component codes plus additional procedures for non-GSP molecular analysis for comparable resources and work for special variant of unknown significance analytics.	
0129U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)	Gap fill		Appealed 2020 crosswalk recommendation. For 2021, requesting Gap fill for component codes plus additional procedures for non-GSP molecular analysis for comparable resources and work for special variant of unknown significance analytics.	

ACLA Recommendations on Molecular Pathology Tier 1 Codes

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
Molecular Pathology Tier 1					
8X003	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence	81298	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	The methodology, resources, and amount of genetic material sequenced are comparable to that of MSH6 full sequence analysis. Both assess germline cancer disposition genes and are relatively the same size.	$641.85
8X004	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)	81334	RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy) gene analysis, targeted sequence analysis (eg, exons 3-8)	The methodology, resources, and amount of genetic material sequenced are comparable to that of RUNX1 targeted sequence analysis. Both assess targeted sequences in cancer-related genes.	$329.51
8X005	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant	81299	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants	The methodology, resources, and amount of genetic material sequenced are comparable to that of MSH6 known familial variants. Both assess known familial variants in germline cancer disposition genes.	$308.00
8X006	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)	81120	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)	The methodology, resources, and amount of genetic material sequenced are comparable to that of IDH1 common variants. Both assess genes for an oncology disorder and similar number of variants.	$193.25
8X008	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)	81272	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18)	The methodology, resources, and amount of genetic material sequenced are comparable to that of KIT targeted sequence analysis	$329.51
8X009	IGH@/BCL2(t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative	81315	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative	The methodology, resources, and amount of genetic material sequenced are comparable to that of PML/RARalpha translocation analysis	$207.31
8X010	CCND1/IGH(t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed	81315	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative	The methodology, resources, and amount of genetic material sequenced are comparable to that of PML/RARalpha translocation analysis	$207.31

ACLA Recommendations on Genomic Sequence Procedure Code

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
New - Genomic Sequence Procedure (GSP)					
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	81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)	81443 is a CPT for severe inherited conditions that must include 15 genes. The testing is performed by NGS. The new epilepsy code is for a severe inherited condition that must include 24 genes and is performed by NGS. The methodology and amount of resources for NGS epilepsy testing is similar to 81443.	$2,448.56

ACLA Recommendations on MAAA and Administrative MAAA Codes

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2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
New - Multianalyte Assays with Algorithmic Analyses					
81XX4	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis	87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets	Both codes represent infectious agents, 3-5 analytes, multiplex amplified probe assays and are run on the same instrumentation.	$142.63
New - Administrative Multianalyte Assays with Algorithmic Analyses					
0014M	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]) using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years	0003M x 0.35	Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and nonalcoholic steatohepatitis (NASH)	0014M is similar in clinical use to 0003M. 3 vs 10 analytes, but specialized immunoassays are more costly, so recommend a multiplier of 0.35 of 0003M	NLA ($503.40 x 0.35) = $176.19
003XM	Adrenal cortical carcinoma, biochemical assay of 25 steroid markers (eg, 5-pregneneriol, 5-pregnenediol, tetrahydrodeoxycortisol, androsterone, etiocholanolone, cortisol, prenanetriol, pregnenediol) utilizing 24 hour urine collection and clinical parameters (age, gender, mode of discovery, tumor diameter, unenhanced CT, hormonal excess, collection duration, urine volume), prognostic algorithm reported as a clinical risk and integrated with steroid assay to report final clinicalsteroid risk for adrenal cortical carcinoma, other malignancy than adrenal cortical carcinoma (eg, sarcoma, liposarcoma, lymphoma metastases from tumors elsewhere) and benign adrenal cortical adenoma.	0003U x 2	Oncology (ovarian) biochemical assays of five proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score	Similar methodology (LC-MS/MS High Resolution Accurate Mass) Multiplier of 2 reflects the increased resources required to analyze 25 steroids (vs. 5 proteins) and the inclusion of 6 clinical parameters, taking into account economies of scale.	NLA ($950.00 x 2) = $1900.00

ACLA Recommendations on Microbiology Codes

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
New - 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	**Option 1** - U0003 If CMS does not allow crosswalk to U0003 then ACLA recommends option 2 **Option 2** - 87502	**Option 1** - U0003 - 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, making use of high throughput technologies as described by CMS-2020-01-R. **Option 2** - 87502 - Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types	**Option 1** - U0003 represents lab testing that would fall under the high throughput category. The U0003 rate represents a close approximation of the lab resources required for this test. **Option 2** - 87502, influenza virus by nucleic acid technology, is similar to the COVID-19 test, CPT 87635. Both tests detect multiple types of virus and are both performed by amplified probe technique. Therefore, 87635 is similar to 87502 in the resources and materials required for the testing.	**Option 1** - $100.00 **Option 2** - $95.80
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	**Option 1** - U0003 If CMS does not allow crosswalk to U0003 then ACLA recommends option 2 **Option 2** - 87502	**Option 1** - U0003 - 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, making use of high throughput technologies as described by CMS-2020-01-R. **Option 2** - 87502 - Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types	**Option 1** - U0003 represents lab testing that would fall under the high throughput category. The U0003 rate represents a close approximation of the lab resources required for this test. **Option 2** - 87502, influenza virus by nucleic acid technology, is similar to the COVID-19 test, U0002. Both tests detect multiple types of virus and can be both performed by amplified probe technique. Therefore, U0002 is similar to 87502 in the resources and materials required for the testing.	**Option 1** - $100.00 **Option 2** - $95.80

ACLA Recommendations on Microbiology Codes (cont'd)

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
New - Microbiology					
U0003	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, making use of high throughput technologies as described by CMS-2020-01-R	U0003 Rate		ACLA recommends that CMS retain the rate of $100.00 that was previously set by CMS.	
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	U0004 Rate		ACLA recommends that CMS retain the rate of $100.00 that was previously set by CMS.	

ACLA Recommendations on Immunology Code

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
New - Immunology					
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	86794 x 2.5	Antibody; Zika virus, IgM	Agrees with Medicare Administrative Contractor (MAC) pricing	NLA ($16.85 x 2.5) = $42.13

ACLA Recommendations on Chemistry and Therapeutic Drug Codes

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
New - Chemistry					
81XX3	Alcohol (ethanol); any specimen except urine and breath, immunoassay (eg, IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)	83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified	Represents the methodology and resources required to perform the assay.	$17.27
82XX1	Estradiol; free, direct measurement (eg, equilibrium dialysis)	82670	Estradiol	Recommendation was obtained for similar work and resources. Free Estradiol is performed by the same method as Estradiol.	$27.94
New - Therapeutic Drug Assays					
80XXX	Acetaminophen	80299	Quantitation of therapeutic drug, not elsewhere specified	This code represents similar methodology and resources to perform the testing.	$18.64
80XX2	Amiodarone	80155	Caffeine	This code is performed by LC-MS/MS methodology and has similar work and resources.	$38.57
80XX1	Salicylate	80299	Quantitation of therapeutic drug, not elsewhere specified	This code represents similar methodology and resources to perform the testing.	$18.64
80XX3	Carbamazepine; 10,11-Epoxide	80155	Caffeine	This code is performed by LC-MS/MS methodology and has similar work and resources.	$38.57
80XX4	Felbamate	80199	Tiagabine	This code represents similar methodology and resources to perform the testing and is used to treat seizures/epilepsy.	$27.11
80XX5	Flecainide	80155	Caffeine	This code is performed by LC-MS/MS methodology and has similar work and resources.	$38.57
80XX6	Itraconazole	80187	Posaconazole	This code represents similar methodology and resources to perform the testing and is used to treat antifungal infections.	$27.11
80XX7	Leflunomide	80230	Infliximab	This code represents similar methodology and resources to perform the testing and is used for inflammatory disorders.	$38.57
80XX8	Methotrexate	80230	Infliximab	This code represents similar methodology and resources to perform the testing and is used for inflammatory disorders.	$38.57
802XX	Rufinamide	80199	Tiagabine	This code represents similar methodology and resources to perform the testing and is used to treat seizures/epilepsy.	$27.11

ACLA Recommendations for the PLA Codes

American Clinical Laboratory Association

- For the annual meeting, ACLA elected to take a "wait and see" approach to comment on many of the PLA codes, as we did not have optics into the rationale for the code holder's recommendation. However, some stakeholders approached us with their rationale that we support. These are listed below.

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
PLA codes (Proprietary Laboratory Analyses)					
0151U	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 results BioFire® FilmArray® Pneumonia Panel BioFire® Diagnostics	Gap fill		No similar test to crosswalk to exists that accounts for the costs and resources of this test.	
+0157U	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) CustomNext + RNA: APC Ambry Genetics®	81201	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence	Crosswalk RNA for single gene APC to 81201 (APC full sequence analysis). Test includes similar gene content, lab process and resources as 81201.	$780.00
+0158U	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) CustomNext + RNA: MLH1 Ambry Genetics®	81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Crosswalk RNA for single gene MLH1 to 81292 (MLH1 full sequence analysis). Test includes similar gene content, lab process and resources as 81292.	$675.40

ACLA Recommendations on PLA Codes (cont'd)

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
PLA codes (Proprietary Laboratory Analyses)					
+0159U	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) CustomNext + RNA: MSH2 Ambry Genetics®	81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Crosswalk RNA for single gene MSH2 to 81295 (MSH2 full sequence analysis). Test includes similar gene content, lab process and resources as 81295.	$381.70
+0160U	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) CustomNext + RNA: MSH6 Ambry Genetics®	81298	MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Crosswalk RNA for single gene MSH6 to 81298 (MSH6 full sequence analysis). Test includes similar gene content, lab process and resources as 81298.	$641.85
+0161U	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) CustomNext + RNA: PMS2 Ambry Genetics®	81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis	Crosswalk RNA for single gene PMS2 to 81317 (PMS2 full sequence analysis). Test includes similar gene content, lab process and resources as 81317.	$676.50

ACLA Recommendations on PLA Codes (cont'd)

American Clinical Laboratory Association

2021 AMA Place-holder	2021 Long Code Descriptor	ACLA Crosswalk Recommendation	Descriptor	ACLA Rationale for CLFS Crosswalk or Gapfill requests	2021 NLA
PLA codes (Proprietary Laboratory Analyses)					
+0162U	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) CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2) Ambry Genetics®	81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11	Crosswalk RNA four-gene panel to 81435 (Hereditary colon cancer disorders (eg. Lynch Syndrome)). Test includes similar gene content, lab process and resources as 81435.	$584.90
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s) Resolution ctDx Lung™, Resolution Bioscience, Resolution Bioscience, Inc	Gap fill		No similar test to crosswalk to exists that accounts for the costs and resources of this test.	