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## Proprietary Laboratory Analyses (PLA)

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Proprietary Laboratory Analyses (PLA) codes represent proprietary laboratory services. «The following codes may include a range of laboratory tests including, but not limited to multianalyte assays with algorithmic analyses (MAAA), genomic sequencing procedures (GSP), biomarker test and pharmacogenomic tests». MAAs are procedures that utilize multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid-based assays (for example, proteins, polypeptides, lipids, carbohydrates). Consistent with CPT® coding guidelines, when a PLA code is available, the specific PLA code takes precedence.

### **«Biomarker and Pharmacogenetic Testing»**

Medi-Cal covers medically necessary biomarker and pharmacogenomic testing, as described in the *Pathology: Molecular Pathology* manual section. Medi-Cal may not cover all PLA codes associated with a particular biomarker or pharmacogenomic test. If Medi-Cal does not cover the particular biomarker or pharmacogenomic test code, it may be covered with an approved *Treatment Authorization Request (TAR)* if medical necessity is established, as described in the *TAR and Non-Benefit: Introduction to List* section of the Provider Manual.

### **Biomarker Testing**

Biomarker testing is used to diagnose, treat, manage or monitor a Medi-Cal member's disease or condition to guide treatment decisions. As defined by Section 14132.09 of the *Welfare and Institutions Code*, biomarker testing is the analysis of an individual's tissue, blood or other biospecimen for the presence of a biomarker. Biomarker testing includes, but is not limited to, single-analyte tests, multiplex panel tests and whole genome sequencing. Biomarkers are a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention. A biomarker includes but is not limited to gene mutations or protein expression. Medically necessary biomarker testing is subject to utilization controls and evidence-based clinical practice guidelines.»

«When testing for biomarkers, all Medi-Cal providers must ensure that they are provided in a manner that limits disruptions to care. As with all Medi-Cal benefits, restricted or denied use of biomarker testing for the purpose of diagnosis, treatment or ongoing monitoring of any medical condition is subject to Medi-Cal's grievance, appeal and State Fair Hearing processes, as well as any additional processes established specifically for Medi-Cal managed care plans.»

### **Table of Proprietary Laboratory Analyses (PLA) Codes**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0017M Oncology (diffuse large b-cell lymphoma [dlbcl]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin embedded tissue, algorithm reported as cell of origin	One of the following ICD-10-CM diagnosis codes is required on the claim: C83.30, C83.31, C83.32, C83.33, C83.34, C83.35, C83.36, C83.37, C83.38, C83.39	Once in a lifetime
0001U Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0003U 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	The following ICD-10-CM diagnosis code is required on the claim: R19.09  Reimbursable for females who meet the following criteria: <ul style="list-style-type: none"> <li>• 18 years of age or older</li> </ul> Ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist	Once in a lifetime, with TAR/SAR override
0007U Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service	N/A	N/A
0016U Oncology (hematolymphoid neoplasia), RNA, NCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation	One of the following ICD-10-CM diagnosis codes is required on the claim: C92.10 thru C92.12	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0017U Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected	One of the following ICD-10-CM diagnosis codes is required on the claim: D45, D47.1 or D47.3	N/A
0018U Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy	The service requires a TAR. A TAR requires documentation of the following criteria: The patient is under evaluation for thyroid nodule(s) The cytopathology result from fine needle aspiration is indeterminate, defined as one of the following: Follicular lesion of undetermined significance (FLUS), Bethesda III, or Atypia of undetermined significance (AUS), Bethesda III, or Follicular neoplasm, Bethesda IV The diagnostic or treatment strategy will be contingent on test results	Once in a lifetime, with TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0022U Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider.	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• Patient has a diagnosis of non-small cell lung cancer (NSCLC).</li><li>• Treatment is contingent on test results</li></ul>	Once in a lifetime, with TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0023U</p> <p>Oncology (acute myelogenous leukemia), DNA, gentotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin.</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00 thru C92.02, C92.60 thru C92.62, C92.A0 thru C92.A2</p>	<p>N/A</p>
<p>0026U</p> <p>Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative, low probability of malignancy").</p>	<p>The service requires a TAR.</p> <p>A TAR requires documentation of the following criteria:</p> <ol style="list-style-type: none"> <li>1. The patient is under evaluation for thyroid nodule(s)</li> </ol> <p>The cytopathology result from fine needle aspiration is indeterminate, defined as one of the following:</p> <ol style="list-style-type: none"> <li>a. Follicular lesion of undetermined significance (FLUS), Bethesda III, or</li> </ol> <p>Atypia of undetermined significance (AUS), Bethesda III, or</p> <p>Follicular neoplasm, Bethesda IV</p> <p>The diagnostic or treatment strategy will be contingent on test results</p>	<p>Once in a lifetime, with TAR/SAR override</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0027U JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15.	One of the following ICD-10-CM diagnosis codes is required on the claim: D45, D47.1 or D47.3	N/A
0034U TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(e.g., thiopurine metabolism), gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5).	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• That the patient is undergoing thiopurine therapy, and</li><li>• The patient has severe or prolonged myelosuppression</li></ul>	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0035U</p> <p>Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative</p>	<p>The service requires a TAR.</p> <p>A TAR requires documentation of the following criteria:</p> <p>1. Rapidly progressive dementia, and</p> <p>At least two out of the following four clinical features:</p> <p>b. Myoclonus</p> <p>Visual or cerebellar signs</p> <p>Pyramid/extrapyramidal signs</p> <p>Akinetic mutism</p> <p>A positive result on at least one of the following tests:</p> <p>c. A typical EEG (periodic sharp wave complexes) during an illness of any duration</p> <p>High signal in caudate/putamen in magnetic resonance imaging (MRI) brain scan or at least two cortical regions (temporal, parietal occipital) either on diffusion-weighted imaging (DWI) or fluid attenuated inversion recovery (FLAIR)</p> <p>No routine investigations indicating an alternative diagnosis</p>	<p>Once in a lifetime, with TAR/SAR override</p>



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0037U Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden.	The service requires a TAR. «A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has either recurrent, relapsed, refractory, metastatic or advanced stages III or IV cancer, and</li><li>• The patient either has not been previously tested using the same Next Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician, and</li><li>• The decision for additional cancer treatment is contingent on the test results»</li></ul>	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0038U Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative	N/A	N/A
0039U Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity	N/A	N/A
0040U BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative	The following ICD-10-CM diagnosis code is required on the claim: C92.10. Allow TAR/SAR override.	N/A
0041U Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM	N/A	N/A
0042U Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0043U Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM	N/A	N/A
0044U Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG	N/A	N/A
0046U FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative	One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00 thru C92.02, C92.60 thru C92.62, C92.A0 thru C92.A2	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0047U</p> <p>Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score</p>	<p>The coverage policy for Gene Expression Profile (GEP) for prostate cancer is based on the 2019 American Society of Clinical Oncologist (ASCO) Guideline titled, "Molecular Biomarkers in Localized Prostate Cancer: ASCO Guideline.</p> <p>The service requires a TAR.</p> <p>A TAR requires documentation of the following criteria:</p> <ul style="list-style-type: none"> <li>2. For identification of patients with prostate cancer who are most likely to benefit from active surveillance or treatment: <ul style="list-style-type: none"> <li>d. Coverage is limited to Oncotype Dx Prostate. <ul style="list-style-type: none"> <li>i. Oncotype DX Prostate – Use PLA code 0047U</li> </ul> </li> </ul> </li> </ul> <p>The patient must have one of the following:</p> <ul style="list-style-type: none"> <li>i. Higher volume Grade Group 1</li> <li>ii. Favorable intermediate risk (e.g., Grade Group 2, percentage of positive biopsy cores, 50 percent, and no more than one NCCN intermediate-risk factor)</li> <li>iii. Discordant features in their risk stratification (e.g., palpable mass with Grade Group 1)</li> </ul>	<p>Once in a lifetime. Allow TAR/SAR override</p>

(Code 0047U continued on next page)

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
<p>0047U (continued) Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score</p>	<p>iv. Other features associated with progression while on active surveillance (e.g., high PSA density and certain germline or somatic mutations).</p> <p>v. Unfavorable intermediate-risk when considering decisions to proceed with treatment (i.e. add androgen deprivation therapy to radiation).</p> <p>Result of the test, when considered as a whole with routine clinical factors, is likely to influence the decision to proceed with surveillance or treatment.</p> <p>For post-prostatectomy patients who seek guidance on adjuvant vs. salvage radiation:</p> <ul style="list-style-type: none"> <li>– Coverage is limited to Decipher Genomic Classifier</li> <li>– Result of the test, when considered as a whole without routine clinical factors, is likely to affect treatment.</li> </ul>	<p>Once in a lifetime</p>
<p>0049U NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, quantitative</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00 thru C92.02, C92.60 thru C92.62, C92.A0 thru C92.A2</p>	<p>N/A</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
<p>0050U Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00 thru C92.02, C92.60 thru C92.62, C92.A0 thru C92.A2</p>	<p>N/A</p>
<p>0051U Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service</p>	<p>N/A</p>	<p>N/A</p>
<p>0052U Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation</p>	<p>N/A</p>	<p>N/A</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0054U Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0058U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative	One of the following ICD-10-CM diagnosis codes is required on the claim: C4A.0, C4A.10 thru C4A.12, C4A.20 thru C4A.22, C4A.30 thru C4A.39, C4A.51 thru C4A.59, C4A.60 thru C4A.62, C4A.70 thru C4A.72, C4A.8, C4A.9	Once in a lifetime, with TAR/SAR override
0059U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative	One of the following ICD-10-CM diagnosis codes is required on the claim: C4A.0, C4A.10 thru C4A.12, C4A.20 thru C4A.22, C4A.30 thru C4A.39, C4A.51 thru C4A.59, C4A.60 thru C4A.62, C4A.70 thru C4A.72, C4A.8, C4A.9	Once in a lifetime, with TAR/SAR override



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0064U Antibody, Treponema pallidum, total and rapid plasma reagin (RPR), immunoassay, qualitative	N/A	N/A
0065U Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)	N/A	N/A
0068U Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. kruseii, C. tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0077U Immunoglobulin paraprotein (M-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype	N/A	N/A
0081U Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis	One of the following ICD-10-CM diagnosis codes is required on the claim: C69.30 thru C69.32, C69.40 thru C69.42	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0082U Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service	N/A	N/A
0084U Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0087U 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	The following ICD-10-CM diagnosis code is required on the claim: Z94.1	N/A
0088U Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection	The following ICD-10-CM diagnosis code is required on the claim: Z94.0	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0107U Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method.	N/A	N/A
0109U Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0120U Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter	One of the following ICD-10-CM diagnosis codes is required on the claim: C83.30 thru C83.39, C85.20 thru C85.29	N/A
0140U Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0141U 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	N/A	N/A
0142U 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	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0154U Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the 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)	One of the following ICD-10-CM diagnosis codes is required on the claim: C67.0 thru C67.9	Once in a lifetime, with TAR/SAR override
0155U Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (e.g., breast cancer) gene analysis (i.e., 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)	One of the following ICD-10-CM diagnosis codes is required on the claim: C50.011 thru C50.929	Once in a lifetime, with TAR/SAR override



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
<p>0157U APC (APC regulator of WNT signaling pathway) (e.g., familial adenomatosis polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure)</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C18.0 thru C18.9, D12.0 thru D12.9, K63.5, Z86.010</p>	<p>Once in a lifetime, with TAR/SAR override</p>
<p>0158U MLH1 (mutL homolog 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42</p>	<p>Once in a lifetime, with TAR/SAR override</p>
<p>0159U MSH2 (mutS homolog 2) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42</p>	<p>Once in a lifetime, with TAR/SAR override</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0160U MSH6 (mutS homolog 6) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once in a lifetime, with TAR/SAR override
0161U PMS2 (PMS1 homolog 2, mismatch repair system component) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once in a lifetime, with TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0162U Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)	One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once in a lifetime, with TAR/SAR override
0165U Peanut allergen-specific quantitative assessment of epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy.	One of the following ICD-10-CM diagnosis codes is required on the claim: Z01.82, Z91.010	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0166U Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0169U NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (e.g., drug metabolism) gene analysis, common variants	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• That the patient is undergoing thiopurine therapy, and</li><li>• The patient has severe or prolonged myelosuppression.</li></ul>	N/A
0171U Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	One of the following ICD-10-CM diagnosis codes is required on the claim: C92.00, C92.01, C92.02, C92.10 thru C92.22, C95.10, D45, D46.0, D46.1, D46.20 thru D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z, D47.1, D47.3.	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0172U Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	The service requires a TAR. A TAR requires documentation of the following criteria: <ol style="list-style-type: none"><li>1. The patient has advanced ovarian, fallopian tube or primary peritoneal cancer</li><li>2. Treatment is contingent on the result of the test</li></ol>	Once in a lifetime, with a TAR/SAR override
0177U Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status	The service requires a TAR. A TAR requires documentation of the following criteria: <ol style="list-style-type: none"><li>1. The patient has confirmed diagnosis of breast cancer</li><li>2. Treatment is contingent the result of the test</li></ol>	Once in a lifetime, with a TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0178U Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction.</p>	<p>N/A</p>	<p>50/day, with a TAR/SAR override</p>
<p>0180U Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons</p>	<p>N/A</p>	<p>N/A</p>
<p>0181U Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1</p>	<p>N/A</p>	<p>N/A</p>
<p>0182U Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10</p>	<p>N/A</p>	<p>N/A</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0183U Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19	N/A	N/A
0184U Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	N/A	N/A



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0185U Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	N/A	N/A
0186U Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	N/A	N/A
0187U Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0188U Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	N/A	N/A
0189U Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2	N/A	N/A
0190U Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3	N/A	N/A
0191U Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0192U Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9	N/A	N/A
0193U Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	N/A	N/A
0194U Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0195U KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)	N/A	N/A
0196U Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0197U Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1	N/A	N/A
0198U Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5	N/A	N/A
0199U Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0200U Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	N/A	N/A
0202U Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0210U Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0216U Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	One of the following ICD-10-CM diagnosis codes is required on the claim: G11.0, G11.3, G11.9, G11.10, G11.11, G11.19, R26.0, R27.0.  Allow TAR/SAR override.	N/A



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0217U Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	One of the following ICD-10-CM diagnosis codes is required on the claim: G11.0, G11.3, G11.9, G11.10, G11.11, G11.19, R26.0, R27.0.  Allow TAR/SAR override.	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0218U Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• Patient has a clinical diagnosis of dystrophinopathy based on the history, physical examination and elevated creatine kinase (CK) level</li><li>• Result of the DMD (dystrophin) deletion or duplication is negative</li></ul>	N/A
0219U Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility	One of the following ICD-10-CM diagnosis codes is required on the claim: B20, Z21. Allow TAR/SAR override.	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0221U Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene	N/A	N/A
0222U Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0223U Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	N/A	N/A
0224U Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed	Do Not Report with CPT code 86769.	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0225U Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	N/A	N/A
0226U Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0227U 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	N/A	N/A
0230U AR (androgen receptor) (e.g., 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	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has clinical signs or symptoms suspicious for bulbar muscular atrophy, and</li><li>• The patient requires the service as a confirmatory test for spinal and bulbar muscular atrophy</li></ul>	Once in a lifetime

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0231U CACNA1A (calcium voltage-gated channel subunit alpha 1A) (e.g., 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	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has clinical signs or symptoms suspicious for Episodic ataxia type 2 (EA2), and</li><li>• The patient requires the service as a confirmatory test for EA2</li></ul>	N/A
0232U CSTB (cystatin B) (e.g., 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	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has clinical signs or symptoms suspicious for myoclonic epilepsy type 1 and requires the service as a confirmatory test for myoclonic epilepsy type 1, and</li><li>• Treatment will be contingent on test results</li></ul>	Once in a lifetime

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0233U FXN (frataxin) (e.g., 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	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has clinical signs or symptoms suspicious for Friedreich ataxia (FRDA), and</li><li>• The patient requires the service as a confirmatory test for FRDA</li></ul>	Once in a lifetime
0234U MECP2 (methyl CpG binding protein 2) (e.g., 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	The service requires a TAR. A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has clinical signs or symptoms suspicious for Rett syndrome, and</li><li>• The patient requires the service as a confirmatory test for Rett syndrome</li></ul>	Once in a lifetime



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0235U PTEN (phosphatase and tensin homolog) (e.g., 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</p>	<p>The service requires a TAR. A TAR requires documentation of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Individual with a personal history of: <ul style="list-style-type: none"> <li>– Bannayan-Riley-Ruvalcaba syndrome, or</li> <li>– Adult Lhermitte-Duclos disease, or</li> <li>– Autism spectrum disorder AND macrocephaly, or</li> <li>– Two or more biopsy-proven trichilemmomas, or</li> <li>– Two or more major criteria (one macrocephaly), or</li> <li>– Three major criteria without macrocephaly, or</li> <li>– One major and three or more minor criteria, or</li> <li>– Four or more minor criteria (please see list below)</li> </ul> </li> <li>2. At-risk individual <ul style="list-style-type: none"> <li>– With a relative who has a clinical diagnosis of Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome for whom testing has not been performed AND who has any one major criterion or two minor criteria</li> </ul> </li> </ol>	<p>N/A</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0235U (continued) PTEN (phosphatase and tensin homolog) (e.g., 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	<u><b>Clinical Criteria:</b></u> Major Criteria <ul style="list-style-type: none"> <li>• Breast Cancer</li> <li>• Mucocutaneous lesions</li> <li>• One biopsy-proven trichilemmoma</li> <li>• Multiple palmoplantar keratosis</li> <li>• Multifocal or extensive oral mucosal papillomatosis</li> <li>• Multiple cutaneous facial papules (often verrucous)</li> <li>• Macular pigmentation of glans penis</li> <li>• Macroencephaly (megalencephaly, ie, ≥97th percentile)</li> <li>• Endometrial cancer</li> <li>• Non-medullary thyroid cancer</li> <li>• Multiple GI tract hamartomas or ganglioneuromas</li> </ul>	N/A

(Code 0235U continued on next page)

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0235U (continued)</p> <p>PTEN (phosphatase and tensin homolog) (e.g., 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</p>	<p>Minor Criteria</p> <ul style="list-style-type: none"> <li>• Other thyroid lesions (adenoma, nodule, goiter)</li> <li>• Mental retardation (IQ ≤75)</li> <li>• Autism spectrum disorder</li> <li>• Single GI tract hamartoma or ganglioneuroma</li> <li>• Fibrocystic disease of the breast</li> <li>• Lipomas</li> <li>• Fibromas</li> <li>• Renal cell carcinoma</li> <li>• Uterine fibroids</li> </ul>	N/A
<p>0236U</p> <p>SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (e.g., spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions</p>	<p>The service requires a TAR.</p> <p>One of the following ICD-10-CM diagnosis codes is required on the claim: O09.00 thru O09.93, Z31.430, Z31.440, Z34.00 thru Z34.03, Z34.80 thru Z34.83, Z34.90 thru Z34.93. Allow TAR/SAR override</p>	Once in a lifetime

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
<p>0237U</p> <p>Cardiac ion channelopathies (e.g., 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</p>	<p>The service requires a TAR.</p> <p>The TAR must document a copy of the report of the physician interpreted 12-lead electrocardiogram (ECG) with pattern consistent with or suspicious for prolonged QT interval. The TAR must also have clinical documentation of one or more of the following:</p> <ol style="list-style-type: none"> <li>1. Torsade de pointes in the absence of drugs known to prolong QT interval</li> <li>2. T-wave alternans</li> <li>3. Notched T-wave in three leads</li> <li>4. Syncope</li> <li>5. Family members with long QT syndrome</li> <li>6. Sudden death in family members less than 30 years of age without defined cause</li> </ol>	<p>N/A</p>
<p>0238U</p> <p>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</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: C17.0 thru C20, C24.0 thru C25.9, C54.0 thru C54.9, C65.1 thru C66.9, C71.0 thru C71.9, D23.0 thru D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42</p>	<p>Once in a lifetime</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0239U 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	The service requires a TAR. A TAR requires documentation of the following criteria: <ol style="list-style-type: none"><li>1. The patient has a diagnosis of either:<ul style="list-style-type: none"><li>– Non-small cell lung cancer (plasma), or</li><li>– Metastatic castrate resistant prostate cancer</li></ul></li><li>2. Treatment is contingent on the test result.</li></ol>	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0240U 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	N/A	N/A
0241U 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	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0242U</p> <p>Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements</p>	<p>The service requires a TAR.</p> <p>«A TAR requires documentation of the following numbered criteria:»</p> <ol style="list-style-type: none"> <li>1. The patient has a diagnosis of either; <ul style="list-style-type: none"> <li>– Non-small cell lung cancer, or</li> <li>– Hormone receptor-positive, Human Epidermal Growth Factor Receptor 2 (HER2)-negative breast cancer</li> </ul> </li> <li>2. Treatment is contingent on the test result.</li> </ol>	<p>Once in a lifetime</p>
<p>0244U</p> <p>Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue</p>	<p>The service requires a TAR</p> <p>A TAR requires documentation of the following criteria:</p> <p><u>For Somatic Testing</u></p> <ul style="list-style-type: none"> <li>• The patient has either recurrent, relapsed, refractory, metastatic or advanced stages III or IV cancer, and</li> <li>• The patient either has not been previously tested using the same Next Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician, and</li> <li>• The decision for additional cancer treatment is contingent on the test results.</li> </ul>	<p>N/A</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0244U (continued)	<u>For Germline Testing</u> <ul style="list-style-type: none"><li>• Ovarian or breast cancer; and</li><li>• Clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer (ie, American College of Obstetrician and Gynecologists' criteria for further genetic evaluation for hereditary (germline) breast and ovarian cancer) and</li><li>• A risk factor for germline (inherited) breast or ovarian cancer; and (BRCA1, BRCA2, Myriad, Claus, Boadicea, or Tyrer Cuzick)</li><li>• Has not been previously tested with the same germline test using NGS for the same germline genetic content.</li></ul>	N/A



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0245U</p> <p>Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage</p>	<p>The service requires a TAR</p> <p>A TAR requires documentation of the following criteria:</p> <ol style="list-style-type: none"> <li>1. The patient is under evaluation for thyroid nodule(s)</li> <li>2. The cytopathology result from fine needle aspiration is indeterminate, defined as one of the following:               <ol style="list-style-type: none"> <li>a. Follicular lesion of undetermined significance (FLUS), Bethesda III, or</li> <li>b. Atypia of undetermined significance (AUS), Bethesda III, or</li> <li>c. Follicular neoplasm, Bethesda IV.</li> </ol> </li> <li>3. The diagnostic or treatment strategy will be contingent on test results</li> </ol>	<p>Once in a lifetime</p>
<p>0246U</p> <p>Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens</p>	<p>N/A</p>	<p>N/A</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0268U Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid	The service requires a TAR A TAR requires documentation of the following criteria: <ol style="list-style-type: none"><li>1. The patient has clinical signs of symptoms for atypical hemolytic uremic syndrome (aHUS), and</li><li>2. The patient requires the service as a diagnostic test for aHUS</li></ol>	Once in a lifetime
0269U Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid	The service requires a TAR A TAR requires documentation of the following criteria: <ol style="list-style-type: none"><li>1. The patient has clinical signs of symptoms suspicious for autosomal dominant congenita thrombocytopenia, and</li><li>2. The patient requires the service as a diagnostic test for autosomal dominant congenital thrombocytopenia</li></ol>	Once in a lifetime
0271U Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	One of the following ICD-10-CM diagnosis codes is required on the claim: D70.0, D70.1, D70.2, D70.3, D70.4, D70.8, and D70.9. TAR over-ride allowed for ICD-10 codes	Once in a lifetime

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0275U Hematology (heparin-induced thrombocytopenia), platelet antibody reactivity by flow cytometry, serum	N/A	N/A
0276U «Genomic sequence analysis of 42 genes for detection of abnormalities associated with inherited thrombocytopenia (low platelet count)»	The service requires a TAR A TAR requires documentation of the following criteria: 1. The patient has clinical signs or symptoms suspicious for inherited thrombocytopenia, and 2. The patient requires the service as a diagnostic test for inherited thrombocytopenia	Once in a lifetime
0279U Hematology (von willebrand disease [vwd]), von willebrand factor (vwf) and collagen iii binding by enzyme-linked immunosorbent assays (elisa), plasma, report of collagen iii binding	N/A	N/A
0280U Hematology (von willebrand disease [vwd]), von willebrand factor (vwf) and collagen iv binding by enzyme-linked immunosorbent assays (elisa), plasma, report of collagen iv binding	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0281U Hematology (von willebrand disease [vwd]), von willebrand propeptide, enzyme-linked immunosorbent assays (elisa), plasma, diagnostic report of von willebrand factor (vwf) propeptide antigen level	N/A	N/A
0282U Red blood cell antigen typing, dna, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes	N/A	N/A
0283U Von willebrand factor (vwf), type 2b, platelet-binding evaluation, radioimmunoassay, plasma	N/A	N/A
0284U Von willebrand factor (vwf), type 2n, factor viii and vwf binding evaluation, enzyme-linked immunosorbent assays (elisa), plasma	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0286U CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	The service requires a TAR A TAR requires documentation of the following criteria: <ul style="list-style-type: none"> <li>• That the patient is undergoing thiopurine therapy, and</li> <li>• The patient has severe or prolonged myelosuppression</li> </ul>	N/A
0287U Oncology (thyroid), DNA and mRNA, next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high)	The service requires a TAR. A TAR requires documentation of the following criteria: <ol style="list-style-type: none"> <li>1. The patient is under evaluation for thyroid nodule(s), and</li> <li>2. The cytopathology result from fine needle aspiration is indeterminate, defined as one of the following:               <ol style="list-style-type: none"> <li>a. Follicular lesion of undetermined significance (FLUS), Bethesda III, or</li> <li>b. Atypia of undetermined significance (AUS), Bethesda III, or</li> <li>c. Follicular neoplasm, Bethesda IV.</li> </ol> </li> <li>3. The diagnostic or treatment strategy will be contingent on test results</li> </ol>	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0301U Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR)	N/A	N/A
0302U Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR); following liquid enrichment	N/A	N/A
«0311U Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)?based antimicrobial susceptibility for each organisms identified	N/A	One unit per day Allow TAR/SAR override»

«Table of Proprietary Laboratory Analyses (PLA) Codes (continued)»

Code and Code Description	TAR and/or Billing Requirements	Frequency
«0312U Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment	N/A	One unit per day Allow TAR/SAR override»
«0314U Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant	N/A	One unit per day Allow TAR/SAR override»

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0321U Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique	N/A	One unit per day Allow TAR/SAR override
0323U Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi	N/A	One unit per day Allow TAR/SAR override



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0326U Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	A TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced stage III or IV solid tumor that did not originate from the central nervous system, and</li><li>• The patient is untreated for the cancer being tested or the patient is not responding to treatment, and</li><li>• The decision for additional cancer treatment is contingent on the test results, and</li><li>• The patient is medically unable to undergo invasive biopsy or tumor tissue testing is not feasible.</li></ul>	Once in a lifetime  Allow TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0327U Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed	N/A	«Reimbursement will be limited to one of the following Noninvasive Prenatal Tests per pregnancy: PLA code 0327U or CPT code 81420 or CPT code 81507. Concurrent or repeat use of these services during the same pregnancy is not covered unless there is documentation of medical necessity.»

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0328U</p> <p>Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service</p>	<p>N/A</p>	<p>One unit per day</p> <p>Allow TAR/SAR override</p>
<p>0329U</p> <p>Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations</p>	<p>«A TAR requires documentation of the following criteria:</p> <p><u>For Somatic Testing</u></p> <ul style="list-style-type: none"> <li>• The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and</li> <li>• The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and</li> </ul> <p>The decision for additional cancer treatment is contingent on the test results.»</p>	<p>«Once in a lifetime»</p> <p>Allow TAR/SAR override</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0333U Oncology (liver), surveillance for hepatocellular carcinoma (hcc) in highrisk patients, analysis of methylation patterns on circulating cell-free dna (cfdna) plus measurement of serum of afp/afp-I3 and oncoprotein des-gammacarboxy-prothrombin (dcp), algorithm reported as normal or abnormal result	N/A	Once in a lifetime

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0334U Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin embedded (ffpe) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	A TAR requires documentation of the following criteria: <u>For Somatic Testing</u> <ul style="list-style-type: none"> <li>• The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and</li> <li>• The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and</li> <li>• The decision for additional cancer treatment is contingent on the test results.</li> </ul>	Once in a lifetime  Allow TAR/SAR override
0339U Oncology (prostate), mrna expression profiling of hoxc6 and dlx1, reverse transcription polymerase chain reaction (rt-pcr), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer	One of the following ICD-10-CM diagnosis codes is required on the claim: C61, D07.5. Allow TAR/SAR override.	Once in 36 months  Allow TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0341U Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid	N/A	Once in a lifetime

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0352U Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphaera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0359U Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer	Reimbursable for males who meet the following criteria: <ul style="list-style-type: none"><li>• 40 years of age or older</li><li>• One of the following ICD-10-CM diagnosis codes is required on the claim: N40.0, N40.1, N40.2, N40.3, Z12.5, Z80.42</li></ul>	Twice per year  Allow TAR/SAR override
0364U Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (pcr) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (mrd) with quantitation of disease burden, when appropriate	One of the following ICD-10-CM diagnosis codes is required on the claim: C90.00, C90.01, C90.02, C91.00, C91.01, C91.02, C91.10, C91.11, C91.12. Allow TAR/SAR override.	N/A



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0369U Infectious agent detection by nucleic acid (dna and rna), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique	N/A	Once per year Allow TAR/SAR override
0371U Infectious agent detection by nucleic acid (dna or rna), genitourinary pathogen, semiquantitative identification, dna from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qpcr), urine	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0372U Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score	N/A	N/A
0373U Infectious agent detection by nucleic acid (dna and rna), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen	N/A	Two times per year  Allow TAR/SAR override
0374U Infectious agent detection by nucleic acid (dna or rna), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine	N/A	N/A

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0378U</p> <p>Rfc1 (replication factor c subunit 1), repeat expansion variant analysis by traditional and repeat-primed pcr, blood, saliva, or buccal swab</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: G11.0, G11.2, G11.3, G11.4, G11.8, G11.9, G11.10, G11.11, G11.19, G32.81, G60.2, G80.4, R26.0, R27.0. Allow TAR/SAR override.</p>	<p>Once in a lifetime</p> <p>Allow TAR/SAR override</p>
<p>0379U</p> <p>Targeted genomic sequence analysis panel, solid organ neoplasm, dna (523 genes) and rna (55 genes) by next-generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden</p>	<p>A TAR requires documentation of the following criteria:</p> <p><u>For Somatic Testing</u></p> <ul style="list-style-type: none"> <li>• The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and</li> <li>• The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and</li> <li>• The decision for additional cancer treatment is contingent on the test results.</li> </ul>	<p>Once in a lifetime</p> <p>Allow TAR/SAR override</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
<p>0381U Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of allo-isoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (lc-ms/ms)</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: E71.0, E71.2. Allow TAR/SAR override.</p>	<p>N/A</p>
<p>0382U Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (lc-ms/ms)</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: E70.0 and E70.1. Allow TAR/SAR override.</p>	<p>N/A</p>
<p>0383U Tyrosinemia type i monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (lc-ms/ms)</p>	<p>One of the following ICD-10-CM diagnosis codes is required on the claim: E70.20, E70.21, E70.29. Allow TAR/SAR override.</p>	<p>N/A</p>

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

Code and Code Description	TAR and/or Billing Requirements	Frequency
0388U Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection	TAR requires documentation of the following criteria: <ul style="list-style-type: none"> <li>• The patient has a diagnosis of non-small cell lung cancer</li> <li>• The patient is medically unable to undergo invasive biopsy or tumor tissue testing is not feasible</li> </ul> Management is contingent on the test results	Once in a Lifetime  Allow TAR/SAR override
0391U Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice-site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score	A TAR requires documentation of the following criteria: <u>For Somatic Testing</u> <ul style="list-style-type: none"> <li>• The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and</li> <li>• The patient either has not been previously tested using the same Next-Generation Sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and</li> </ul> The decision for additional cancer treatment is contingent on the test results.	Once in a lifetime  Allow TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
0408U Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])	N/A	N/A
0409U Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability	TAR requires documentation of the following criteria: <ul style="list-style-type: none"><li>• The patient has a diagnosis of non-small cell lung cancer, and</li><li>• The patient is medically unable to undergo invasive biopsy or tumor tissue testing is not feasible, and</li><li>• Management is contingent on the test results</li></ul>	Once in a lifetime Allow TAR/SAR override

**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

<b>Code and Code Description</b>	<b>TAR and/or Billing Requirements</b>	<b>Frequency</b>
<p>0448U</p> <p>Oncology (lung and colon cancer), DNA, qualitative, next-generation sequencing detection of single-nucleotide variants and deletions in EGFR and KRAS genes, formalin-fixed paraffin-embedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options</p>	<p>A TAR requires documentation of the following criteria:</p> <ul style="list-style-type: none"> <li>• The patient has been diagnosed with either non-small cell lung cancer (NSCLC) or colorectal cancer, and</li> </ul> <p>Management is contingent on the test results</p>	<p>Once in a lifetime</p> <p>Allow TAR/SAR override</p>
<p>&lt;&lt;0471U</p> <p>Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin-fixed paraffin-embedded (FFPE), predictive, identification of detected mutations</p>	<p>A TAR requires documentation of the following criteria:</p> <ul style="list-style-type: none"> <li>• The patient has been diagnosed with colorectal cancer, and</li> <li>• Management is contingent on the test results.</li> </ul>	<p>Once in a lifetime</p> <p>Allow TAR/SAR override&gt;&gt;</p>

«Table of Proprietary Laboratory Analyses (PLA) Codes (continued)

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0473U Oncology (solid tumor), next-generation sequencing (NGS) of DNA from formalin-fixed paraffin-embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden</p>	<p>A TAR requires documentation of the following criteria: <u>For Somatic Testing</u></p> <ul style="list-style-type: none"> <li>• The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and</li> <li>• The patient either has not been previously tested using the same next-generation sequencing (NGS) test for the same primary diagnosis of cancer or repeat testing using the same NGS test only occurs when a new primary cancer diagnosis is made by the treating physician, and</li> <li>• The decision for additional cancer treatment is contingent on the test results.</li> </ul> <p>Independent of the above criteria, somatic testing may be approved if the test is approved by the U.S. Food and Drug Administration (FDA) as a companion diagnostic device, and the decision for additional treatment is contingent on the test results.</p>	<p>Once in a lifetime  Allow TAR/SAR override»</p>



**Table of Proprietary Laboratory Analyses (PLA) Codes (continued)**

«Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0475U</p> <p>Hereditary prostate cancer-related disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer</p>	<p>A TAR requires documentation of the following criteria:</p> <p><u>For Germline Testing</u></p> <ul style="list-style-type: none"> <li>• The patient has prostate cancer, and</li> <li>• The patient has a clinical indication for germline (inherited) testing for hereditary cancer (e.g., NCCN Guidelines for Prostate Cancer), and</li> <li>• The patient has a risk factor for germline (inherited) cancer (e.g., NCCN Guidelines for Prostate Cancer), and</li> <li>• The patient has not been previously tested with the same germline genetic content.</li> </ul>	<p>Once in a lifetime</p> <p>Allow TAR/SAR override»</p>

«Table of Proprietary Laboratory Analyses (PLA) Codes (continued)

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0488U</p> <p>Obstetrics (fetal antigen noninvasive prenatal test), cell-free dna sequence analysis for detection of fetal presence or absence of 1 or more of the rh, c, c, d, e, duffy (fya) or kell (k) antigen in alloimmunized pregnancies, reported as selected antigen(s) detected or not detected</p>	<p>A TAR requires documentation of the following criteria:</p> <p><u>For fetal RhD status</u></p> <ul style="list-style-type: none"> <li>• The patient is currently pregnant, and</li> <li>• The pregnant patient is RhD negative, and</li> <li>• The pregnant patient has not been tested with another cell-free DNA test for fetal RhD status during the same pregnancy.</li> </ul> <p><u>For fetal status of non-RhD red blood cell (RBC) antigens</u></p> <ul style="list-style-type: none"> <li>• The patient is currently pregnant, and</li> <li>• The pregnant patient has alloantibodies to one or more non-RhD RBC antigens, and</li> <li>• The paternal non-RhD RBC antigen status is either heterozygous or unknown, and</li> <li>• The pregnant patient has not been tested with another cell-free DNA test to determine fetal status of non-RhD RBC antigens during the same pregnancy.</li> </ul> <p>Reimbursement will be limited to once per pregnancy, unless there is documentation of medical necessity.</p>	<p>N/A»</p>

«Table of Proprietary Laboratory Analyses (PLA) Codes (continued)

Code and Code Description	TAR and/or Billing Requirements	Frequency
<p>0494U Red blood cell antigen (fetal rhd gene analysis), next-generation sequencing of circulating cell-free dna (cfdna) of blood in pregnant individuals known to be rhd negative, reported as positive or negative</p>	<p>A TAR requires documentation of the following criteria: <u>For fetal RhD status</u></p> <ul style="list-style-type: none"> <li>• The patient is currently pregnant, and</li> <li>• The pregnant patient is RhD negative, and</li> <li>• The pregnant patient has not been tested with another cell-free DNA test to determine fetal RhD status during the same pregnancy.</li> </ul> <p>Reimbursement will be limited to once per pregnancy, unless there is documentation of medical necessity.</p>	<p>N/A»</p>

## **Legend**

Symbols used in the document above are explained in the following table.

<b>Symbol</b>	<b>Description</b>
<<	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
>>	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.