

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81105 – 81112 Human Platelet Antigen Genotyping	No	One of the following ICD-10-CM diagnosis codes is required on the claim (except with valid TAR): D69.51 or P61.0	Once-in-a-lifetime, any provider, except with valid TAR override	
81120 IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble), common variants	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): C71.0 – C71.9 or C92.00 – C92.02	Once-in-a-lifetime, any provider, except with valid TAR override	
81121 IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial), common variants	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): C71.0 – C71.9 or C92.00 – C92.02	Once-in-a-lifetime, any provider, except with valid TAR override	
81161 DMD (dystrophin) deletion analysis, and duplication analysis, if performed	No	ICD-10-CM diagnosis code G71.00 (muscular dystrophy) G71.01, G71.02 or G71.09 is required on the claim.	Once-in-a-lifetime, any provider, except with valid TAR override	
81162 BRCA1, BRCA2 gene analysis; full sequence analysis and full duplication/deletion analysis <i>Continued below</i>	Yes	A TAR for code 81162 requires documentation as follows: 1) The patient has personal or family history that suggests an inherited cancer susceptibility based on a standard assessment tool: <u>See Attachment B</u> for an example or one of the following tools: <ul style="list-style-type: none"> Ontario Family History Assessment Tool Manchester Scoring System Referral Screening Tool Pedigree Assessment Tool 	Once-in-a-lifetime, any provider, except with valid TAR override *	See Attachment B – Family History Screening Tool which is suggested for use prior to ordering BRCA testing Note that for the purpose of this policy, a “close blood relative” is defined as a first-degree, second-degree or third-degree blood relative. First degree relatives are biological parents, siblings, and children. Second-degree relatives are biological grandparents, aunts, uncles, nephews, nieces, grandchildren and half-siblings. (<i>Cont’d</i>)

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<p><i>Continued from above</i></p> <p>81162</p> <p>BRCA1, BRCA2 gene analysis; full sequence analysis and full duplication/deletion analysis</p> <p><i>Continued below</i></p>	<p>Yes</p>	<ul style="list-style-type: none"> • 7-Question Family History Screening Tool • International Breast Cancer Intervention Study instrument • Brief versions of BRCAPRO; AND <p>2) The patient is willing to talk with a health professional who is suitably trained to provide genetic counseling and interpret test results; AND</p> <p>3) The test results will aid in the decision-making</p> <p>Additionally, a TAR for code 81162 requires documentation of <i>one or more</i> of the following numbered criteria</p> <p>Per NCCN Guidelines Version 1.2020 Hereditary Cancer Testing Criteria, testing is clinical indicated in the following scenarios:</p> <p>1) An individual from a family with a known pathogenic /likely pathogenic variant in cancer susceptibility gene mutation; OR</p> <p>2) Individuals meeting criteria below and previously tested NEGATIVE in single gene analysis desiring multiple gene sequencing</p> <p>3) Personal history of cancer</p> <ul style="list-style-type: none"> • Diagnosed at ≤45 years of age; OR • Diagnosed at 46 - 50 yo with: <ul style="list-style-type: none"> - An unknown or limited family history; OR - An additional breast cancer primary at any age - One or more close blood relatives with breast, ovarian, pancreatic or prostate cancer (Gleason score ≥7) • Diagnosed at ≤60 years of age with triple negative breast cancer; OR • Diagnosed at any age with: <ul style="list-style-type: none"> - One or more close blood relatives with: <ul style="list-style-type: none"> o breast cancer diagnosed at ≤50 years of age; or o Ovarian carcinoma; or 	<p>Once-in-a-lifetime, any provider, except with valid TAR override *</p>	<p>Where third degree blood relatives are mentioned, they include great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p> <p>See Attachment B – Family History Screening Tool which is suggested for use prior to ordering BRCA testing</p> <p>Note that for the purpose of this policy, a “close blood relative” is defined as a first-degree, second-degree or third degree blood relative.</p> <p>First degree relatives are biological parents, siblings, and children. Second-degree relatives are biological grandparents, aunts, uncles, nephews, nieces, grandchildren and half-siblings.</p> <p>Where third degree blood relatives are mentioned, they include great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.</p>

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<p><i>Continued from above</i></p> <p>81162</p> <p>BRCA1, BRCA2 gene analysis; full sequence analysis and full duplication/deletion analysis</p> <p><i>Continued below</i></p>	<p>Yes</p>	<ul style="list-style-type: none"> ○ Male breast cancer; or ○ Metastatic prostate cancer; or ○ Pancreatic cancer - 2 or more additional diagnoses of breast cancer at any age in patient and/or in close blood relatives; or • Ashkenazi Jewish ancestry; OR • Personal history of Male Breast Cancer; or • Personal history of Ovarian carcinoma (includes fallopian tube cancer and peritoneal cancer); or • Personal history of pancreatic cancer; or • Personal history of metastatic prostate cancer (biopsy-proven and/or with radiographic evidence; include distant metastasis and regional bed or nodes; not biochemical recurrence); or • Personal history of high-grade prostate cancer (Gleason score ≥ 7) at any age with: <ul style="list-style-type: none"> - Ashkenazi Jewish ancestry; or - One or more close blood relatives with ovarian carcinoma, pancreatic cancer or metastatic prostate cancer at any age or breast cancer under 50 years of age; or - 2 or more close blood relatives with breast or prostate cancer (any grade) at any age • A mutation identified on tumor genomic testing that has clinical implications if also identified in the germ line • To aid in systemic therapy decision-making <p>4) Family History of Cancer</p> <ul style="list-style-type: none"> • An affected or unaffected individual with first- or second degree-blood relative meeting any criteria above (except those meeting criteria ONLY for systemic therapy decisions) 	<p>Once-in-a-lifetime, any provider, except with valid TAR override *</p>	<p>See Attachment B – Family History Screening Tool which is suggested for use prior to ordering BRCA testing</p> <p>Note that for the purpose of this policy, a “close blood relative” is defined as a first-degree, second-degree or third degree blood relative.</p> <p>First degree relatives are biological parents, siblings, and children. Second-degree relatives are biological grandparents, aunts, uncles, nephews, nieces, grandchildren and half-siblings.</p> <p>Where third degree blood relatives are mentioned, they include great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>

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<p><i>Continued from above</i></p> <p>81162</p> <p>BRCA1, BRCA2 gene analysis; full sequence analysis and full duplication/deletion analysis</p>	Yes	<ul style="list-style-type: none"> An affected or unaffected individual who does NOT meet criteria but has a probability of greater than or equal to 5% of at BRCA 1 / 2 pathogenic variant based on prior probability models <p>For BRACAnalysis CDx testing for breast cancer, all of the following TAR criteria must be met:</p> <ul style="list-style-type: none"> Patient has metastatic breast cancer. Patient is human epidermal growth factor receptor 2 (HER2)-negative. Patient has previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patient's additional treatment is contingent on the test results. <p>* An approved TAR that meets the necessary criteria listed below to override the once-in-a-lifetime frequency is required:</p> <p>In Advanced Ovarian Cancer: For patients with previous germline BRCA test (blood sample), additional somatic BRCA testing (tumor sample) may be necessary when treatment with Lynparza™ (olaparib) is contingent on the test results.</p>	Once-in-a-lifetime, any provider, except with valid TAR override *	<p>See Attachment B – Family History Screening Tool which is suggested for use prior to ordering BRCA testing</p> <p>Note that for the purpose of this policy, a “close blood relative” is defined as a first-degree, second-degree or third degree blood relative.</p> <p>Where third degree blood relatives are mentioned, they include great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p> <p>Olaparib has FDA approval for use in some Ovarian Cancer diagnosis where there is a mutation in the germline or somatic BRCA.</p>
<p>81163</p> <p>BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) gene analysis; full sequence analysis</p>	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	

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81164 BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) gene analysis; full duplication/deletion analysis	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	
81165 BRCA1 (BRCA1, DNA repair associated) gene analysis; full sequence analysis	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	
81166 BRCA1 (BRCA1, DNA repair associated) gene analysis; full duplication/deletion analysis	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	
81167 BRCA2 (BRCA2, DNA repair associated) gene analysis; full duplication/deletion analysis	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	
81168 CCND1/IGH (t[11;14])(eg. mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed	No	One of the following ICD-10-CM diagnosis codes is required on the claim: C83.10 thru C83.19	Once-in-a-lifetime, any provider, except with valid TAR override	
81170 ALB1 gene analysis, variants in the kinase domain	Yes	Requires documentation on the TAR that the recipient has chronic myeloid leukemia (CML) and failed tyrosine kinase inhibitor (TKI) therapy	Once-in-a-lifetime, any provider, except with valid TAR override	

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81171 AFF2 (AF4/FMR2 family, member 2 [FMR2]) gene analysis evaluation to detect abnormal alleles	No	One of the following ICD-10-CM diagnosis codes is required on the claim (except with valid TAR): F70, F71, F80.0 – F89, H93.25, R48.0, R62.0 – R62.59, F82, F88, R48.2	Once-in-a-lifetime, any provider, except with valid TAR override	
81172 AFF2 (AF4/FMR2 family, member 2 [FMR2]) gene analysis; characterization of alleles	No	One of the following ICD-10-CM diagnosis codes is required on the claim (except with valid TAR): F70, F71, F80.0 – F89, H93.25, R48.0, R62.0 – R62.59, F82, F88, R48.2	Once-in-a-lifetime, any provider, except with valid TAR override	
81173 AR (androgen receptor) gene analysis; full gene sequence	Yes	A TAR for CPT code 81173 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for bulbar muscular atrophy, and • The patient requires the service as a confirmatory test for spinal and bulbar muscular atrophy 	Once-in-a-lifetime, any provider, except with valid TAR override	
81174 AR (androgen receptor) gene analysis; known familial variant	Yes	A TAR for CPT code 81174 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for bulbar muscular atrophy, and • The patient requires the service as a confirmatory test for spinal and bulbar muscular atrophy 	Once-in-a-lifetime, any provider, except with valid TAR override	
81175 ASXL gene analysis, full gene sequence	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): C93.10 – C93.12, D46.0 – D46.C, D47.1	Once-in-a-lifetime, any provider, except with valid TAR override	

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81176 ASXL gene analysis, targeted sequence analysis	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): C93.10 – C93.12, D46.0 – D46.C, D47.1	Once-in-a-lifetime, any provider, except with valid TAR override	
81177 ATN1 (atrophin 1) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81177 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for dentatorubral pallidoluysian atrophy, and • The patient requires the service as a confirmatory test for dentatorubral pallidoluysian atrophy 	Once-in-a-lifetime; any provider, except with valid TAR override	
81178 ATXN1 (ataxin 1) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81178 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 1 (SCA1), and • The patient requires the service as a confirmatory test for SCA1 	Once-in-a-lifetime, any provider, except with valid TAR override	
81179 ATXN2 (ataxin 2) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81179 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 2 (SCA2), and • The patient requires the service as a confirmatory test for SCA2 	Once-in-a-lifetime, any provider, except with valid TAR override	
81180 ATXN3 (ataxin 3) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81180 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 3 (SCA3), and • The patient requires the service as a confirmatory test for SCA3 	Once-in-a-lifetime, any provider, except with valid TAR override	

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81181 ATXN7 (ataxin 7) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81181 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 7 (SCA7), and • The patient requires the service as a confirmatory test for SCA7 	Once-in-a-lifetime, any provider, except with valid TAR override	
81182 ATXN8OS (ATXN8 opposite strand [non-protein coding]) gene analysis, evaluation to detect abnormal	Yes	A TAR for CPT code 81182 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 8 (SCA8), and • The patient requires the service as a confirmatory test for SCA8 	Once-in-a-lifetime, any provider, except with valid TAR override	
81183 ATXN10 (ataxin 10) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81183 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 10 (SCA10), and • The patient requires the service as a confirmatory test for SCA10 	Once-in-a-lifetime, any provider, except with valid TAR override	
81184 CACNA1A (calcium voltage-gated channel subunit alpha1 A) gene analysis; evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81184 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Episodic ataxia type 2 (EA2), and • The patient requires the service as a confirmatory test for EA2 	Once-in-a-lifetime, any provider, except with valid TAR override	
81185 CACNA1A (calcium voltage-gated channel subunit alpha1 A) gene analysis; full gene sequence	Yes	A TAR for CPT code 81185 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Episodic ataxia type 2 (EA2), and • The patient requires the service as a confirmatory test for EA2 	Once-in-a-lifetime, any provider, except with valid TAR override	

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81186 CACNA1A (calcium voltage-gated channel subunit alpha1 A) gene analysis; known familial variant	Yes	A TAR for CPT code 81186 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Episodic ataxia type 2 (EA2), and • The patient requires the service as a confirmatory test for EA2 	Once-in-a-lifetime, any provider, except with valid TAR override	
81187 CNBP (CCHC-type zinc finger nucleic acid binding protein) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81187 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Myotonic dystrophy type 2 (MD2), and • The patient requires the service as a confirmatory test for MD2 	Once-in-a-lifetime, any provider, except with valid TAR override	
81188 CSTB (cystatin B) gene analysis; evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81188 requires documentation of the following criteria: <ul style="list-style-type: none"> • 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 • Treatment will be contingent on test results 	Once-in-a-lifetime, any provider, except with valid TAR override	
81189 CSTB (cystatin B) gene analysis; full gene sequence	Yes	A TAR for CPT code 81189 requires documentation of the following criteria: <ul style="list-style-type: none"> • 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 • Treatment will be contingent on test results 	Once-in-a-lifetime, any provider, except with valid TAR override	
81190 CSTB (cystatin B) gene analysis; known familial variant(s)	Yes	A TAR for CPT code 81190 requires documentation of the following criteria: <ul style="list-style-type: none"> • 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 • Treatment will be contingent on test results 	Once-in-a-lifetime, any provider, except with valid TAR override	

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81191 NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis	Yes	A TAR for CPT code 81191 requires documentation of the following criteria: Adult and pediatric patients with solid tumors with any one of the following clinical scenario: <ul style="list-style-type: none"> • Metastatic tumor or where surgical resection is likely to result in severe morbidity, or • Have no satisfactory alternative treatments or have progressed following treatment 	N/A	
81192 NTRK2 (neurotrophic receptor tyrosine kinase 2)(eg, solid tumors) translocation analysis	Yes	See CPT code 81191 for TAR criteria and billing requirements.	N/A	
81193 NTRK3 (neurotrophic receptor tyrosine kinase 3)(eg, solid tumors) translocation analysis	Yes	See CPT code 81191 for TAR criteria and billing requirements.	N/A	
81194 NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis	Yes	See CPT code 81191 for TAR criteria and billing requirements.	N/A	
81201 APC gene analysis; full gene sequence	No	One of the following ICD-10-CM codes is required on the claim: C18.0 – C18.9, D12.0 – D12.9, K63.5, Z86.010	Once-in-a-lifetime, any provider, except with valid TAR override	
81202 APC gene analysis; known familial variants	Yes	Requires documentation on the Treatment Authorization Request (TAR) of a family history of familial adenomatous polyposis that includes a relative with a known deleterious APC mutation	Once-in-a-lifetime, any provider, except with valid TAR override	

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81203 APC gene analysis; duplication/deletion variants	No	One of the following ICD-10-CM codes is required on the claim: C18.0 – C18.9, D12.0 – D12.9, K63.5, Z86.010	Once-in-a-lifetime, any provider, except with valid TAR override	
81204 AR (androgen receptor) gene analysis; characterization of alleles	Yes	A TAR for CPT code 81204 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for bulbar muscular atrophy, and • The patient requires the service as a confirmatory test for spinal and bulbar muscular atrophy 	Once-in-a-lifetime. any provider, except with valid TAR override	
81206 BCR/ABL1 translocation analysis; major breakpoint	No	One of the following ICD-10-CM codes is required on the claim: C91.00 – C91.02 or C92.10 – C92.12	N/A	
81207 BCR/ABL1 translocation analysis; minor breakpoint	No	One of the following ICD-10-CM codes is required on the claim: C91.00 – C91.02 or C92.10 – C92.12	N/A	
81208 BCR/ABL1 translocation analysis; other breakpoint	No	One of the following ICD-10-CM codes is required on the claim: C91.00 – C91.02 or C92.10 – C92.12	N/A	
81210 BRAF (B-Raf proto-oncogene, serine/threonine kinase), gene analysis, V600 variant(s)	No	One of the following ICD-10-CM codes is required on the claim: C18.0 – C18.9, C19, C20, C33, C34.00 – C34.92, C43.0 – C43.9, C79.2 or D03.0 – D03.9	Once-in-a-lifetime, any provider, except with valid TAR override	
81212 BRCA1, BRCA2 gene analysis; variants	Yes	Requires documentation on the TAR of the following: <ul style="list-style-type: none"> • An individual is of an ethnicity associated with the Ashkenazi Jewish population <p>No additional family history may be required</p>	Once-in-a-lifetime, any provider, except with valid TAR override	See Attachment B - Family History Screening Tool which is suggested for use prior to ordering BRCA testing

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81215 BRCA1 (breast cancer 1) gene analysis; known familial variant	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	
81216 BRCA2 (breast cancer 2) gene analysis; full sequence analysis	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	
81217 BRCA2 (breast cancer 2) gene analysis; known familial variant	Yes	See CPT code 81162 for TAR criteria and billing requirements.	See CPT code 81162	
81218 CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) gene analysis, full gene sequence	No	One of the following ICD-10-CM codes is required on the claim: C92.00 – C92.02, C92.40 – C92.42 or C92.50 – C92.52	Once-in-a-lifetime, any provider, except with valid TAR override	
81219 CALR (calreticulin) gene analysis, common variants in exon 9	No	One of the following ICD-10-CM codes is required on the claim: C92.10 – C92.12, D45, D47.3 or D75.81	Once-in-a-lifetime, any provider, except with valid TAR override	
81220 CFTR (cystic fibrosis transmembrane conductance regulator) gene analysis; common variants	No	When used to bill for cystic-fibrosis screening requires ICD-10-CM codes E84, O09.00 thru O09.93, X38.49, Z31.430, Z31.440, Z31.5, Z34.00 thru Z34.03, Z34.80 thru Z34.83, Z34.90 thru Z34.93 Not reimbursable with code 81224 for same date of service, recipient and provider May be billed separately with an appropriate National Correct Coding Initiative (NCCI) associated modifier Refer to the <i>Genetic Counseling and Screening</i> section in the Medi-Cal Manual for additional information	Once-in-a-lifetime, any provider, except with valid TAR override	

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81221 CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cysticfibrosis) gene analysis; known familial variants	No	The following criteria should be documented: <ul style="list-style-type: none"> • The Patient has a strong clinical presentation suspicious of CF, and • Family with known variant not included in the test for common variants 	Once-in-a-lifetimeany provider, except with valid TAR override	
81222 CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cysticfibrosis) gene analysis; duplication/deletion variants	No	The following criteria should be documented: <ul style="list-style-type: none"> • The patient has a strongclinical presentation suspicious of CF, and • Gene test for common variants did not result in twodisease-causing variants in CFTR 	Once-in-a-lifetimeany provider, except with valid TAR override	
81223 CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cysticfibrosis) gene analysis; full gene sequence	Yes	TAR requires documentation of the following criteria: <ul style="list-style-type: none"> • Patient has intermediate sweat chloride result, or • Patient with confirmed or suspected CF, with unknowngenotype, and additional treatment or assessment of prognosis is contingent on the result of the test, or • Patient with normal sweat chloride results despite a strong clinical suspicion of CF 	Once-in-a-lifetime, any provider, except with valid TAR override	
81224 CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis (eg, male infertility)	No	When used to bill for cystic-fibrosis testing requires ICD-10-CM diagnosis code N46.9	Once-in-a-lifetime, any provider, except with valid TAR override	
81225 CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19), gene analysis, common variants	No	Billable with any valid ICD-10-CM diagnosis code.	Once-in-a-lifetime, any provider, except with valid TAR override	

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81232 DPYD (dihydropyrimidine dehydrogenase) gene analysis, common variant(s)	Yes	A TAR requires documentation of the following criteria: <ul style="list-style-type: none">• Patient had severe and unexpected toxicity (such as myelosuppression, mucositis, diarrhea, neurotoxicity, cardiotoxicity) during treatment with Fluorouracil or Capecitabine chemotherapy.	Once-in-a-lifetime, any provider, except with valid TAR override	
81233 BTK (Bruton's tyrosine kinase) gene analysis, common variants	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): D80.0 – D80.6, C91.10 – C91.12, C83.00 – C83.09	Once-in-a-lifetime, any provider, except with valid TAR override	
81234 DMPK (DM1 protein kinase) gene analysis; evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81234 requires documentation of the following criteria: <ul style="list-style-type: none">• The patient has clinical signs or symptoms suspicious for myotonic dystrophy type 1 (MD1), and• The patient requires the service as a diagnostic test for MD1.	Once-in-a-lifetime, any provider, except with valid TAR override	
81235 EGFR (epidermal growth factor receptor) gene analysis, common variants	No	One of the following ICD-10-CM codes is required on the claim: C33, C34.00 – C34.92	Once-in-a-lifetime, any provider, except with valid TAR override	
81236 EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) gene analysis, full gene sequence	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): D47.1, D47.3, C83.30 – C83.39	Not more than once per month	
81237 EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) gene analysis, common variant(s)	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): D47.1, D47.3, C83.30 – C83.39	Not more than once per month	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81238 F9 (coagulation factor IX) full gene analysis sequence	No	ICD-10-CM code D67 is required on the claim (except with valid TAR)	Once-in-a-lifetime, any provider, except with valid TAR override	
81239 DMPK (DM1 protein kinase) gene analysis; characterization of alleles	Yes	A TAR for CPT code 81239 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for myotonic dystrophy type 1 (MD1), and • The patient requires the service as a diagnostic test for MD1. 	Once-in-a-lifetime, any provider, except with valid TAR override	
81243 FMR1 (fragile X mental retardation 1) gene analysis; evaluation to detect abnormal alleles	No	One of the following ICD-10-CM codes is required on the claim: F70, F71 – F73, F78, F80.0 – F84.2, F88, F89, H93.25, R48.2, R62.0, R62.50 – R62.59	Once-in-a-lifetime, any provider, except with valid TAR override	
81244 FMR1 (fragile X mental retardation 1) gene analysis; characterization of alleles	No	One of the following ICD-10-CM codes is required on the claim: F70, F71 – F73, F78, F80.0 – F84.2, F88, F89, H93.25, R48.2, R62.0, R62.50 – R62.59	Once-in-a-lifetime, any provider, except with valid TAR override	
81245 FLT3 (fms-related tyrosine kinase 3), gene analysis; internal tandem duplication (ITD) variants	No	One of the following ICD-10-CM codes is required on the claim: C92.00 – C92.02, C92.60 - C92.62 or C92.A0 – C92.A2	Once-in-a-lifetime, any provider, except with valid TAR override	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81246 FLT3 (fms-related tyrosine kinase 3), gene analysis; tyrosine kinase domain (TKD) variants	No	One of the following ICD-10-CM codes is required on the claim: C92.00 – C92.02, C92.60 - C92.62 or C92.A0 – C92.A2	Once-in-a-lifetime, any provider, except with valid TAR override	
81250 G6PC (glucose-6-phosphatase, catalytic subunit) gene analysis, common variants	Yes	The patient has clinical features suspicious for, or requires the laboratory service as a diagnostic test for glycogen storage disease, type 1a	Once-in-a-lifetime, any provider, except with valid TAR override	
81256 HFE (hemochromatosis) gene analysis, common variants	No	One of the following ICD-10-CM codes is required on the claim: E83.10, E83.110 or E83.118 – E83.119	Once-in-a-lifetime, any provider, except with valid TAR override	
81257 HBA1/HBA2 (alpha globin 1 and alpha globin 2), gene analysis; common deletions or variant	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	
81258 HBA1/HBA2 (alpha globin 1 and alpha globin 2), gene analysis; known familial variant	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	
81259 HBA1/HBA2 (alpha globin 1 and alpha globin 2), gene analysis; full gene sequence	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81260 IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinas complex-associated protein) gene analysis, common variants	No	Indicated for: <ul style="list-style-type: none"> • Hypotonia in infancy • Decreased or absent deep tendon reflexes • Decreased taste and absence of fungiform papillae of the tongue • Absence of overflow tears with emotional crying (alacrima) • Absence of axon flare response after intradermal histamine injection • Pupillary hypersensitivity to parasympathomimetic agents 	Once-in-a-lifetime, any provider, except with valid TAR override	While DHCS requires a TAR for this test, PHC has chosen to have no TAR requirement.
81265 Comparative analysis using Short Tandem Repeat markers	No	One of the following ICD-10-CM codes is required on the claim: C81.00 – C96.9, D45, T86.00 – T86.09 or T86.5	Once-in-a-lifetime, any provider, except with valid TAR override	
81266 Comparative analysis using Short Tandem Repeat markers; each additional specimen	No	One of the following ICD-10-CM codes is required on the claim: C81.00 – C96.9, D45, T86.00 – T86.09 or T86.5	Once-in-a-lifetime, any provider, except with valid TAR override	
81267 Chimerism (engraftment) analysis, post transplantation specimen; without cell selection	No	One of the following ICD-10-CM codes is required on the claim: T86.01, T86.02, T86.09 or T86.5	N/A	
81268 Chimerism (engraftment) analysis, post transplantation specimen; with cell selection	No	One of the following ICD-10-CM codes is required on the claim: T86.01, T86.02, T86.09 or T86.5	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81269 HBA1/HBA2 (alpha globin 1 and alpha globin 2), gene analysis; duplication/deletion variants	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	
81270 JAK2 (Janus kinase 2) gene analysis, p. Val617Phe (V617F) variant	No	One of the following ICD-10-CM codes is required on the claim: C91.00 – C91.02, D45, D47.1 or D47.3	Once-in-a-lifetime, any provider, except with valid TAR override	
81271 HTT (huntingtin) gene analysis; evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81271 requires documentation of the following criteria: <ul style="list-style-type: none"> • For adults, the patient has unequivocal motor signs of Huntington’s disease (HD) and requires the service to confirm the diagnosis • For children, the patient has a family history of HD and develops symptoms that raise the suspicion for juvenile-onset HD as exemplified by two or more of the following: <ul style="list-style-type: none"> – Declining school performance – Seizures – Oral motor dysfunction – Rigidity – Gait disturbance 	Once-in-a-lifetime, any provider, except with valid TAR override	
81272 KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog), gene analysis, targeted sequence analysis	No	One of the following ICD-10-CM codes is required on the claim: C43.70 - C43.72, C92.00 – C92.02, C92.40 – C92.42, C92.50 – C92.52, D03.70 – D03.72, D47.01, D47.02 or D48.1	Once-in-a-lifetime, any provider, except with valid TAR override	
81273 KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog), gene analysis, D816 variant(s)	No	One of the following ICD-10-CM codes is required on the claim: C96.20 – C96.29, D47.01, D47.02	Once-in-a-lifetime, any provider, except with valid TAR override	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81274 HTT (huntingtin) gene analysis; characterization of alleles	Yes	A TAR for CPT code 81274 requires documentation of the following criteria: <ul style="list-style-type: none"> • For adults, the patient has unequivocal motor signs of Huntington’s disease (HD) and requires the service to confirm the diagnosis • For children, the patient has a family history of HD and develops symptoms that raise the suspicion for juvenile-onset HD as exemplified by two or more of the following: <ul style="list-style-type: none"> – Declining school performance – Seizures – Oral motor dysfunction – Rigidity – Gait disturbance 	Once-in-a-lifetime, any provider, except with valid TAR override	
81275 KRAS (Kirsten rat sarcoma viral oncogene homolog) gene analysis; variants in exon 2	No	One of the following ICD-10-CM codes is required on the claim: C18.0 – C20, D01.1, D01.2, D01.40, D01.49, D37.4 or D37.5	Once-in-a-lifetime, any provider, except with valid TAR override	
81276 KRAS (Kristen rat sarcoma viral oncogene homolog) gene analysis; additional variant(s)	No	One of the following ICD-10-CM codes is required on the claim: C18.0, C18.2 – C20, D01.1, D01.2, D01.40, D01.49, D37.4 or D37.5	Once-in-a-lifetime, any provider, except with valid TAR override	
81278 IGH @/BLC2 (t[4; 18]) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative	Yes	A TAR for CPT code 81278 requires documentation of the following criteria: The patient has clinical features suspicious for, or requires the service as a diagnostic test for follicular lymphoma	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81279 JAK2 (Janus kinase 2)(eg, myeloproliferative disorder) gene analysis, (eg, exons 12and 13)	No	One of the following ICD-10-CM codes is required on the claim: C91.00 thru C91.02, D45, D47.1 or D47.3	N/A	
81283 IFNL3 (interferon, lambda 3), gene analysis, rs12979860 variant	No	ICD-10-CM code B18.2 is required on the claim (except with valid TAR)	Once-in-a-lifetime, any provider, except with valid TAR override	
81284 FXN (frataxin) gene analysis; evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81284 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Friedreich ataxia (FRDA), and • The patient requires the service as a confirmatory test for FRDA 	Once-in-a-lifetime, any provider, except with valid TAR override	
81285 FXN (frataxin) gene analysis; characterization of alleles	Yes	A TAR for CPT code 81285 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Friedreich ataxia (FRDA), and • The patient requires the service as a confirmatory test for FRDA 	Once-in-a-lifetime, any provider, except with valid TAR override	
81286 FXN (frataxin) gene analysis; full gene sequence	Yes	A TAR for CPT code 81286 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has clinical signs or symptoms suspicious for Friedreich ataxia (FRDA), and • The patient requires the service as a confirmatory test for FRDA 	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81287 MGMT (0-6 methylguanin-DNA methyltransferase) methylation analysis	No	Indicated for: <ul style="list-style-type: none"> The patient has the diagnosis of glioblastoma multiforme, and Treatment strategy will be contingent on the test results Reimbursable when billed with ICD-10: C71.9. 	Once-in-a-lifetime, any provider, except with valid TAR override	While DHCS requires a TAR for this test, PHC has chosen to have no TAR requirement when billed with ICD-10 code C71.9
81288 MLH1 gene analysis; promoter methylation analysis	Yes	Document the following criteria on the TAR: <ul style="list-style-type: none"> Patient with cancer(s) associated with Lynch Syndrome, and The tumor demonstrates microsatellite instability or immunohistochemistry results indicating loss of MLH1 protein expression 	Once-in-a-lifetime, any provider, except with valid TAR override	
81289 FXN (frataxin) gene analysis; known familial variant(s)	Yes	A TAR for CPT code 81289 requires documentation of the following criteria: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for Friedreich ataxia (FRDA), and The patient requires the service as a confirmatory test for FRDA 	Once-in-a-lifetime, any provider, except with valid TAR override	
81292 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) gene analysis; full sequence analysis	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	
81293 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) gene analysis; known familial variants	Yes	Document on the TAR family history of Lynch Syndrome that includes a relative with a known deleterious MLH1 mutation	Once-in-a-lifetime, any provider, except with valid TAR override	Prediction model calculator suggested for use prior to ordering Lynch syndrome testing: http://premm.dfci.harvard.edu/

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81294 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) gene analysis; duplication/deletion variants	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	
81295 MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) gene analysis; full sequence analysis	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	
81296 MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) gene analysis; known familial variants	Yes	Document on the TAR family history of Lynch Syndrome that includes a relative with a known deleterious MSH2 mutation	Once-in-a-lifetime, any provider, except with valid TAR override	Prediction model calculator suggested for use prior to ordering Lynch syndrome testing: http://premm.dfci.harvard.edu/
81297 MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) gene analysis; duplication/deletion variants	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	
81298 MSH6 (mutS homolog 6 [E. coli] gene analysis; full sequence analysis	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	PHC will also reimburse for these ICD-10 codes: C56.1 – C56.9
81299 MSH6 (mutS homolog 6 [E. coli] gene analysis; known familial variants	Yes	Document on the TAR family history of Lynch Syndrome that includes a relative with a known deleterious MSH6 mutation	Once-in-a-lifetime, any provider, except with valid TAR override	Prediction model calculator suggested for use prior to ordering Lynch syndrome testing: http://premm.dfci.harvard.edu/

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81300 MSH6 (mutS homolog 6 [E. coli]) gene analysis; duplication/deletion variants	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	
81301 Microsatellite instability analysis of markers for mismatch repair deficiency includes comparison of neoplastic and normal tissue, if performed	No	Reimbursable for patients who meet one of the following criteria: the patient is diagnosed with one of the Lynch syndrome-associated cancers; or, the patient is diagnosed with an unresectable or metastatic solid tumor and the treatment will be contingent on the test result.	Once-in-a-lifetime, any provider, except with valid TAR override	
81305 MYD88 (myeloid differentiation primary response 88) (gene analysis, p.Leu265Pro (L265P) variant	No	The following ICD-10-CM code is required on the claim (except with valid TAR): C88.0	Once-in-a-lifetime, any provider, except with valid TAR override	
81306 NUDT15 (nudix hydrolase 15) gene analysis, common variant(s)	Yes	A TAR for CPT code 81306 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient is undergoing thiopurine therapy, and • The patient has severe or prolonged myelosuppression. 	Once-in-a-lifetime, any provider, except with valid TAR override	PHC will also authorize 81306 for the purpose of predicting toxicity to azathioprine prior to initiation of treatment for SLE and other recognized conditions when treatment with long term azathioprine is being considered.
81309 PIK3CA gene analysis, targeted sequence analysis	Yes	A TAR/SAR for CPT code 81309 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has confirmed diagnosis of breast cancer • Treatment is contingent on the result of the test 	Once-in-a-lifetime, any provider, except with valid TAR override	
81310 NPM1 (nucleophosmin) gene analysis, exon 12 variants	No	One of the following ICD-10-CM codes is required on the claim: C92.00 – C92.02	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81311 NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) gene analysis, variants in exon 2 and exon 3	No	One of the following ICD-10-CM codes is required on the claim: C18.0, C18.2 – C20, D01.1, D01.2, D01.40, D01.49, D37.4 or D37.5	Once-in-a-lifetime, any provider, except with valid TAR override	
81312 PABPN1 (poly[A] binding protein nuclear 1) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81312 requires documentation of the following criteria: <ul style="list-style-type: none"> • The patient has symptoms of ptosis and dysphagia, and • The patient requires the service as a confirmatory test for Oculopharyngeal Muscular Dystrophy 	Once-in-a-lifetime, any provider, except with valid TAR override	
81314 PDGFRA (platelet-derived growth factor receptor, alpha polypeptide), gene analysis, targeted sequence analysis	No	ICD-10-CM code D48.1 is required on the claim.	Once-in-a-lifetime, any provider, except with valid TAR override	
81315 PML/RAR-alpha (promyelocytic leukemia/retinoic acid receptor alpha) translocation analysis; common breakpoints	No	One of the following ICD-10-CM codes is required on the claim: C92.40 – C92.42	N/A	
81316 PML/RAR-alpha (promyelocytic leukemia/retinoic acid receptor alpha) translocation analysis; single breakpoint	No	One of the following ICD-10-CM codes is required on the claim: C92.40 – C92.42	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81317 PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) gene analysis; full sequence analysis	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	
81318 PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) gene analysis; known familial variants	Yes	Document on the TAR family history of Lynch Syndrome that includes a relative with a known deleterious PMS2 mutation	Once-in-a-lifetime, any provider, except with valid TAR override	Prediction model calculator suggested for use prior to ordering Lynch syndrome testing: http://premm.dfci.harvard.edu/
81319 PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) gene analysis; duplication/deletion variants	No	One of the following ICD-10-CM codes is required on the claim: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030, Z85.038, Z85.040, Z85.048, Z85.42	Once-in-a-lifetime, any provider, except with valid TAR override	
81320 PLCG2 (phospholipase C gamma 2) gene analysis, common variants	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): C91.10 – C91.12	Once-in-a-lifetime, any provider, except with valid TAR override	
81321 PTEN (phosphatase and tensin homolog) gene analysis; full sequence analysis <i>Continued below</i>	Yes <i>Continued</i>	A TAR for CPT-4 code 81321 requires documentation of one or more of the following numbered criteria: 1. Individual with a personal history of: <ul style="list-style-type: none"> • Bannayan-Riley-Ruvalcaba syndrome, or • Adult Lhermitte-Duclos disease, or • Autism spectrum disorder AND macrocephaly, or • Two or more biopsy-proven trichilemmomas, or • Two or more major criteria (one macrocephaly), or • Three major criteria without macrocephaly, or • One major and three or more minor criteria, or • Four or more minor criteria (please see list below) 	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81321</p> <p>PTEN (phosphatase and tensin homolog) gene analysis; full sequence analysis</p>	Yes	<p>2. At-risk individual: 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</p> <p>Major Criteria</p> <ul style="list-style-type: none"> • Breast cancer • Mucocutaneous lesions • One biopsy-proven trichilemmoma • Multiple palmoplantar keratosis • Multifocal or extensive oral mucosal papillomatosis • Multiple cutaneous facial papules (often verrucous) • Macular pigmentation of glans penis • Macroencephaly (megalencephaly, ie, ≥ 97th percentile) • Endometrial cancer • Non-medullary thyroid cancer • Multiple GI tract hamartomas or ganglioneuromas <p>Minor Criteria</p> <ul style="list-style-type: none"> • Other thyroid lesions (adenoma, nodule, goiter) • Mental retardation ($IQ \leq 75$) • Autism spectrum disorder • Single GI tract hamartoma or ganglioneuroma • Fibrocystic disease of the breast • Lipomas • Fibromas • Renal cell carcinoma • Uterine fibroids 	Once-in-a-lifetime, any provider, except with valid TAR override	
<p>81322</p> <p>PTEN gene analysis; known familial variant</p>	Yes	Requires documentation on the TAR that patient is from a family with a known PTEN mutation	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81323 PTEN gene analysis; duplication/deletion variant	Yes	Requires documentation on the TAR of a negative result in the full sequence analysis in PTEN (CPT-4 code 81321), and that patient meets one or more criteria listed under code 81321	Once-in-a-lifetime, any provider, except with valid TAR override	
81329 SMN1 (survival of motor neuron 1, telomeric) gene analysis; dosage/deletion analysis, includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	No	One of the following ICD-10-CM diagnosis codes is required on the claim (except with valid TAR): O09.00 thru O09.93, Z31.430, Z31.440, Z34.00 - Z34.03, Z34.80 - Z34.83, Z34.90 - Z34.93	Once-in-a-lifetime, any provider, except with valid TAR override	
81331 SNRPN/UBE3A methylation analysis	Yes	Document the following age-specific criteria on the TAR <ul style="list-style-type: none"> • <u>Birth to 2 years</u>: Hypotonia with poor suck • <u>2 – 6 years</u>: Hypotonia with history of poor suck and global development delay • <u>6 – 13 years</u>: History of hypotonia with poor suck (hypotonia often persists); global development delay; and excessive eating (hyperphagia; obsession with food) with central obesity if uncontrolled • <u>13 years – adult</u>: Cognitive impairment – usually mild mental retardation; excessive eating (hyperphagia; obsession with food) with central obesity if uncontrolled; and hypothalamic hypogonadism and/or typical behavior problems (including temper tantrums and obsessive-compulsive features) 	Once-in-a-lifetime, any provider, except with valid TAR override	
81334 RUNX1 (runt related transcription factor 1), gene analysis, targeted sequence analysis	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): C92.00 – C92.02, C92.40 – C92.A2	Once-in-a-lifetime, any provider, except with valid TAR override	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81335 TPMT (thiopurine S-methyltransferase), gene analysis, common variants	Yes	The service requires a TAR with documentation of the following criteria: <ul style="list-style-type: none"> That the patient is undergoing thiopurine therapy, and The patient has severe or prolonged myelosuppression. 	Once-in-a-lifetime, any provider, except with valid TAR override	PHC will also authorize 81335 for the purpose of predicting toxicity to azathioprine prior to initiation of treatment for SLE and other recognized conditions when treatment with long term azathioprine is being considered.
81336 SMN1 (survival of motor neuron 1, telomeric) gene analysis; full gene sequence	No	The following criteria should be documented: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for spinal muscular atrophy, and The patient requires the service as a confirmatory test for spinal muscular atrophy 	Once-in-a-lifetime, any provider, except with valid TAR override	
81337 SMN1 (survival of motor neuron 1, telomeric) gene analysis; known familial sequence variant(s)	No	The following criteria should be documented: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for spinal muscular atrophy, and The patient requires the service as a confirmatory test for spinal muscular atrophy 	Once-in-a-lifetime, any provider, except with valid TAR override	
81338 MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A,W515K, W515L, W515R)	Yes	A TAR for CPT code 81338 requires documentation of the following criteria: The patient has clinical features suspicious for, or requires the service as a diagnostic test for, myeloproliferative disorder	N/A	
81339 MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10	Yes	A TAR for CPT code 81339 requires documentation of the following criteria: The patient has clinical features suspicious for, or requires the service as a diagnostic test for, myeloproliferative disorder	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81340 TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction)	Yes	A TAR for CPT code 81340 requires documentation of the following criteria: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for lymphoma and requires the service as a confirmatory test for lymphoma; or The test is used to aid in classification of lymphomas 	Once-in-a-lifetime, any provider, except with valid TAR override	
81341 TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (eg, Southern blot)	Yes	A TAR for CPT code 81341 requires documentation of the following criteria: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for lymphoma and requires the service as a confirmatory test for lymphoma; or The test is used to aid in classification of lymphomas 	Once-in-a-lifetime, any provider, except with valid TAR override	
81342 TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)	Yes	A TAR for CPT code 81342 requires documentation of the following criteria: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for lymphoma and requires the service as a confirmatory test for lymphoma; or The test is used to aid in classification of lymphomas 	Once-in-a-lifetime, any provider, except with valid TAR override	
81343 PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81343 requires documentation of the following criteria: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 12 (SCA12), and The patient requires the service as a confirmatory test for SCA12 	Once-in-a-lifetime, any provider, except with valid TAR override	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81344 TBP (TATA box binding protein) gene analysis, evaluation to detect abnormal alleles	Yes	A TAR for CPT code 81344 requires documentation of the following criteria: <ul style="list-style-type: none"> The patient has clinical signs or symptoms suspicious for spinocerebellar ataxia type 17 (SCA17), and The patient requires the service as a confirmatory test for SCA17 	Once-in-a-lifetime, any provider, except with valid TAR override	
81345 TERT (telomerase reverse transcriptase) gene analysis, targeted sequence analysis	Yes	Document the following criteria on the TAR: The patient has the diagnosis of grade II, III or IV glioma.	Once-in-a-lifetime, any provider, except with valid TAR override	
81347 SF3B1 (splicing factor[3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)	No	One of the following ICD-10-CM codes is required on the claim C92.00 thru C92.02, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, D46.9.	N/A	
81348 SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg,P95H, P95L)	No	One of the following ICD-10-CM codes is required on the claim C92.00 thru C92.02, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, D46.9.	N/A	
81351 TP53 (tumorprotein 53) (eg, Li- Fraumeni syndrome) gene analysis; fullgene sequence <i>Continued Below</i>	Yes	A TAR for CPT code 81351 requires documentation for one of the following numbered criteria: <ol style="list-style-type: none"> All of the following conditions: <ul style="list-style-type: none"> The patient has sarcoma diagnosed before 45 years of age,and A first-degree relative with anycancer before 45 years of age,and 	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81351 TP53 (tumor protein 53) (eg, Li- Fraumeni syndrome) gene analysis; full gene sequence</p>	Yes	<ul style="list-style-type: none"> • A first or second-degree relative with any cancer before 45 years of age, or a sarcoma at any age; or 2. All of the following conditions: <ul style="list-style-type: none"> • A tumor belonging to the Li- Fraumeni Syndrome (LFS) tumorspectrum (soft tissue sarcoma, osteosarcoma, pre-menopausal breast cancer, brain tumor, adrenocortical carcinoma, leukemia or lung bronchoalveolar cancer) before 46 years of age, and • At least one first or second-degree relative with an LFS tumor (except breast cancer if the patient has breast cancer) before 56 years of age or with multiple tumors; or 3. The patient has multiple tumors (except multiple breast tumors), two of which belong to the LFS tumor spectrum, and the first occurred before 46 years of age; or 4. The patient is diagnosed with adrenocortical carcinoma or choroid plexus tumor. 	N/A	
<p>81352 TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)</p>	Yes	See CPT code 81351 for TAR criteria and billing requirements.	N/A	
<p>81353 TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant</p>	Yes	See CPT code 81351 for TAR criteria and billing requirements.	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81357 U2AF1 (U2 small nuclear RNA auxiliaryfactor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg S34F, S34Y, Q157R,Q157P)	No	One of the following ICD-10-CM codes is required on the claim C92.00 thru C92.02, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, D46.9.	N/A	
81360 ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/argine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)	No	One of the following ICD-10-CM codes is required on the claim C92.00 thru C92.02, D46.0, D46.1, D46.20, D46.21, D46.22, D46.A, D46.B, D46.C, D46.4, D46.Z, D46.9.	N/A	
81361 HBB (hemoglobin, subunit beta); common variant(s) (e.g., HbS, HbC, HbE)	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	
81362 HBB (hemoglobin, subunit beta); known familial variant(s)	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	
81363 HBB (hemoglobin, subunit beta); duplication/deletion variant(s)	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81364 HBB (hemoglobin, subunit beta); full gene sequence	No	N/A	Once-in-a-lifetime, any provider, except with valid TAR override	
81370 – 81383 Human Leukocyte Antigen Typing	No TAR required	CPT-4 codes 81370 – 81380, 81382 and 81383 (human leukocyte antigen typing) are reimbursable only with an ICD-10-CM diagnosis in the range of Z94.0 – Z94.9. CPT-4 code 81381 (HLA Class I typing, high resolution, one allele or allele group, each) is only reimbursable with an ICD-10-CM diagnosis of B20, F31.0 – F31.9, G40.001 – G40.919, G50.0, R75, Z01.812, Z21, Z94.0 – Z94.9.	Once-in-a-lifetime, any provider, except with valid TAR override	
81400 Molecular Pathology Procedure, Level 1 <i>Continued below</i>	Yes	Providers are required to document one of the following on the TAR: <ul style="list-style-type: none"> CCR5 (chemokine C-C motif receptor 5): <ul style="list-style-type: none"> Initial test: <ul style="list-style-type: none"> ❖ The use of a CCR5 inhibitor is being considered, or ❖ The patient exhibits virologic failure on a CCR5 inhibitor Subsequent tests: <ul style="list-style-type: none"> ❖ A previous Trofile test was performed including the test date and the results showing that the patient has a CCR5 virus, and, ❖ The patient's previous Trofile test was not less than 90 days from subsequent request, and, ❖ The patient has clinical scenario such as, but not limited to the following: <ul style="list-style-type: none"> • The treatment with CCR5 antagonist drug therapy was interrupted and the clinician wishes to reinstitute CCR5 antagonist drug therapy, or, 	Once-in-a-lifetime, any provider, except with valid TAR override	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<i>Continued from above</i>		<ul style="list-style-type: none"> The patient had a Trofile test performed previously that showed that the recipient had the CCR5 virus, but the CCR5 antagonist drug therapy was never initiated. <p>Claims without documentation showing the preceding criteria have been met will be denied.</p>		

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81401 Molecular Pathology Procedure, Level 2</p> <p><i>Continued below</i></p>	<p>Yes</p> <p><i>Continued</i></p>	<p>Coverage for CPT-4 code 81401 (molecular pathology procedure, Level 2) is limited to the listed services. Reimbursement for code 81401 requires an approved TAR and requires providers to document one of the following on the TAR:</p> <ul style="list-style-type: none"> • ABCC8 (familial hyperinsulinism): <ul style="list-style-type: none"> – The patient has persistent hyperinsulinemic hypoglycemia of infancy (PHHI), failed medical therapy, and – The patient is under evaluation for surgical intervention • ABL (c-abl oncogene 1, receptor tyrosine kinase) – The patient has chronic myeloid leukemia (CML) and failed tyrosine kinase inhibitor (TKI) therapy • ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (e.g., acquired imatinib resistance), T315I variant – The patient has chronic myeloid leukemia (CML) and failed tyrosine kinase inhibitor (TKI) therapy • APOE (apolipoprotein E) (for example, hyperlipoproteinemia type III, cardiovascular disease, Alzheimer disease), common variants (for example, 2, 3, 4) <ul style="list-style-type: none"> – The patient has clinical signs and symptoms consistent with Alzheimer Disease, and – Medical treatment strategy will be contingent on the test results. • DEK/NUP214 (t [6; 9])(e.g., acute myeloid leukemia), translocation analysis, qualitative, and quantitative, if performed – The patient has acute myeloid leukemia and the test is intended for the process of risk stratification • E2A/PBX1 (acute lymphocytic leukemia): 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81401</p> <p>Molecular Pathology Procedure, Level 2</p> <p><i>Continued below</i></p>	<p>Yes</p> <p><i>Continued</i></p>	<ul style="list-style-type: none"> – The patient has the diagnosis of acute lymphocytic/lymphoblastic leukemia, and – Treatment or monitoring strategy will be contingent on the test results • ETV6/RUNX1 (acute lymphocytic leukemia) – The patient has the diagnosis of acute lymphocytic or lymphoblastic leukemia, and requires the test for assessment of cancer prognosis • H19 (Beckwith-Wiedemann syndrome) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Beckwith-Wiedemann syndrome • KCNQ1OT1 (Beckwith-Wiedemann syndrome) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Beckwith-Wiedemann syndrome • MLL/AFF1 (acute lymphoblastic leukemia): <ul style="list-style-type: none"> – The patient has the diagnosis of acute lymphoblastic leukemia, and – Treatment or monitoring strategy will be contingent on the test results • MLL/MLLT3 (acute myeloid leukemia): <ul style="list-style-type: none"> – The patient has the diagnosis of acute myeloid leukemia, and – Treatment or monitoring strategy will be contingent on the test results • MUTYH (MYH-associated polyposis) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for MUTYH- associated polyposis • MT-ATP6 (neuropathy with ataxia and retinitis pigmentosa [NARP], Leigh syndrome) – The patient has clinical features suspicious for, or 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81401</p> <p>Molecular Pathology Procedure, Level 2</p>	<p>Yes</p>	<p>requires the service as a confirmatory test for NARP or Leigh syndrome</p> <ul style="list-style-type: none"> PRSS1 (hereditary pancreatitis): <ul style="list-style-type: none"> – An unexplained documented episode of acute pancreatitis in childhood, or – Recurrent acute attacks of pancreatitis of unknown cause, or – Chronic pancreatitis of unknown cause, particularly with onset younger than 25 years of age, or – A family history of recurrent acute pancreatitis, chronic pancreatitis of unknown cause, and/or childhood pancreatitis of unknown cause consistent with autosomal dominant inheritance PYGM (glycogen storage disease type V, McArdle disease) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for glycogen storage disease type V RUNX1/RUNX1T1 (t[8;21]) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for acute myeloid leukemia <p>Claims without documentation showing the preceding criteria have been met will be denied.</p>	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81402 Molecular Pathology Procedure, Level 3	Yes	<p>Coverage for CPT-4 code 81402 (molecular pathology procedure, Level 3) is limited to the listed services. Reimbursement for code 81402 requires an approved TAR and requires providers to document one of the following on the TAR:</p> <ul style="list-style-type: none"> • Chromosome 1p-/19q- (e.g. glial tumors), deletion analysis – Patient with diagnosis of grade II, III or IV glioma • MEFV (Mediterranean fever) (eg, familial Mediterranean fever), common variants: <ul style="list-style-type: none"> – The patient has clinical signs and symptoms suspicious for familial MEFV, and – The patient requires the service as a confirmatory test for familial MEFV 	Once-in-a-lifetime, any provider, except with valid TAR override	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81403 Molecular Pathology Procedure, Level 4</p> <p><i>Continued below</i></p>	<p>Yes</p>	<p>Coverage for CPT-4 code 81403 (molecular pathology procedure, Level 4) is limited to the listed services. Reimbursement for code 81403 requires an approved TAR and requires providers to document one of the following on the TAR:</p> <ul style="list-style-type: none"> • DNMT3A (acute myeloid leukemia): <ul style="list-style-type: none"> – The patient has diagnosis of acute myeloid leukemia, and – The treatment strategy will be contingent on test results • EPCAM (Lynch syndrome) – The patient has one of the following: <ul style="list-style-type: none"> – Colon cancer – Uterine cancer – Lynch syndrome – Family history of colorectal cancer, uterine cancer or Lynch syndrome – Presence of synchronous, metachronous colorectal or other Lynch-associated tumors • KCNC3 (spinocerebellar ataxia) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for spinocerebellar ataxia • KCNJ11 (familial hyperinsulinism): <ul style="list-style-type: none"> For persistent hyperinsulinemic hypoglycemia of infancy (PHHI) <ul style="list-style-type: none"> ❖ The patient has PHHI and failed medical therapy, and ❖ The patient is under evaluation for surgical intervention For suspected developmental delay, epilepsy and neonatal diabetes (DEND) syndrome: <ul style="list-style-type: none"> ❖ The patient has developmental delay, epilepsy and neonatal diabetes 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	<p>Prediction model calculator suggested for use prior to ordering Lynch syndrome testing: http://premm.dfci.harvard.edu/</p>

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81403</p> <p>Molecular Pathology Procedure, Level 4</p>	<p>Yes</p>	<ul style="list-style-type: none"> ❖ The confirmation of the diagnosis and the treatment strategy is contingent on the test result • KIR (killer cell immunoglobulin-like receptor for hematopoietic stem cell transplantation): <ul style="list-style-type: none"> – The patient has diagnosis of acute myeloid leukemia or multiple myeloma, and <p>The test is used for donor search process for patients considering hematopoietic stem cell transplantation</p> • Known family variant not otherwise specified, for gene listed in Molecular Pathology Procedure Levels 1 - 3 or identified during a genomic sequencing procedure (GSP), DNA sequence analysis, each variant exon: <ul style="list-style-type: none"> – Documentation of the specific gene listed in Molecular Pathology Procedure Levels 1 - 3 or GSP for which further analysis is being requested • MICA (solid organ transplantation): <ul style="list-style-type: none"> – The patient is undergoing evaluation for kidney transplantation, or – The patient is post kidney transplantation <p><i>Continued</i></p>	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81403</p> <p>Molecular Pathology Procedure, Level 4</p>	<p>Yes</p>	<ul style="list-style-type: none"> • NDP (Norrie disease) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Norrie disease • SH2D1A (X-linked lymphoproliferative syndrome) – The patient has a single X chromosome with the diagnosis of: <ul style="list-style-type: none"> – Common variable immune deficiency, or – Hypogammaglobulinemia, or – Hemophagocytic lymphohistiocytosis, or – Severe infectious mononucleosis, or – Lymphoma, or – Family history of X-linked lymphoproliferative syndrome • VHL (von Hippel-Lindau tumor suppressor), deletion/duplication analysis – The patient has clinical features suspicious for, or requires the service as a diagnostic test for von Hippel-Lindau syndrome <p>Claims without documentation showing the preceding criteria have been met will be denied.</p>	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81404 Molecular Pathology Procedure, Level 5</p> <p><i>Continued below</i></p>	<p>Yes</p> <p><i>Continued</i></p>	<p>Coverage for CPT-4 code 81404 (molecular pathology procedure Level 5) is limited to the listed services. Reimbursement for code 81404 requires an approved Treatment Authorization Request (TAR) and requires providers to document one of the following on the TAR:</p> <ul style="list-style-type: none"> ACADS (acyl-CoA dehydrogenase, C-2 to C-3 short chain), targeted sequence analysis: <ul style="list-style-type: none"> The patient has elevated C4-C on newborn screening test, and Confirmation (urine acylglycines or urine organic acids) that C4 (butyrylcarnitine) and/or ethylmalonic acid (EMA) are elevated CD40LG (X-linked hyper IgM syndrome) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for hyperimmunoglobulin M syndromes EMD (Emery-Dreifuss muscular dystrophy) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Emery-Dreifuss muscular dystrophy EPM2A (progressive myoclonus epilepsy) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for progressive myoclonus epilepsy FHL1 (Emery-Dreifuss muscular dystrophy) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Emery-Dreifuss muscular dystrophy MEFV (Mediterranean fever) (eg, familial Mediterranean fever), common variants: <ul style="list-style-type: none"> The patient has clinical signs and symptoms suspicious for familial MEFV, and The patient requires the service as a 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81404</p> <p>Molecular Pathology Procedure, Level 5</p>	<p>Yes</p>	<p>confirmatory test for familial MEFV</p> <ul style="list-style-type: none"> • NDP (Norrie disease) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Norrie disease • PDX1 (pancreatic and duodenal homeobox 1) <ul style="list-style-type: none"> – The patient requires the service as a diagnostic test for (maturity onset diabetes of the young) MODY, and – Is younger than 25 years of age, and – Has a family history of diabetes, and – Has negative islet of autoantibodies • PRNP (genetic prion disease) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for genetic prion disease • PRSS1 (hereditary pancreatitis): <ul style="list-style-type: none"> – An unexplained documented episode of acute pancreatitis in childhood, or – Recurrent acute attacks of pancreatitis of unknown cause, or – Chronic pancreatitis of unknown cause, particularly with onset younger than 25 years of age, or – A family history of recurrent acute pancreatitis, chronic pancreatitis of unknown cause, and/or childhood pancreatitis of unknown cause consistent with autosomal dominant inheritance • RET (ret proto-oncogene), common variants <ul style="list-style-type: none"> – The patient has a personal history of primary C cell hyperplasia, Medullary Thyroid Carcinoma (MTC), or Multiple Endocrine Neoplasia (MEN), type 2B, or – The patient has a family history consistent with MEN, type 2B or MTC, 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	
<p><i>Continued below</i></p>	<p><i>Continued</i></p>			

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81404</p> <p>Molecular Pathology Procedure, Level 5</p>	<p>Yes</p>	<p>and at risk for autosomal dominant inheritance of the syndrome</p> <ul style="list-style-type: none"> • SH2D1A (X-linked lymphoproliferative syndrome) – The patient has a single X chromosome with the diagnosis of: <ul style="list-style-type: none"> – Common variable immune deficiency, or – Hypogammaglobulinemia, or – Hemophagocytic lymphohistiocytosis, or – Severe infectious mononucleosis, or – Lymphoma, or – Family history of X-linked lymphoproliferative syndrome • SPINK1 (hereditary pancreatitis): <ul style="list-style-type: none"> – An unexplained documented episode of acute pancreatitis in childhood, or – Recurrent acute attacks of pancreatitis of unknown cause, or – Chronic pancreatitis of unknown cause, particularly with onset younger than 25 years of age, or – A family history of recurrent acute pancreatitis, chronic pancreatitis of unknown cause, and/or childhood pancreatitis of unknown cause consistent with autosomal dominant inheritance • VHL (von Hippel-Lindau tumor suppressor), full gene sequence - the patient has clinical features suspicious for, or requires the service as a diagnostic test for von Hippel-Lindau syndrome <p>Claims without documentation showing the preceding criteria have been met will be denied.</p>	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81405 Molecular Pathology Procedure, Level 6</p> <p><i>Continued below</i></p>	<p>Yes</p> <p><i>Continued</i></p>	<p>Coverage for CPT-4 code 81405 (molecular pathology procedure, level 6) is limited to the listed services. Reimbursement for code 81405 requires an approved TAR and requires providers to document one of the following on the TAR:</p> <ul style="list-style-type: none"> • ABCD1 (adrenoleukodystrophy): <ul style="list-style-type: none"> – The patient has clinical features suspicious for adrenoleukodystrophy, and – Measurement of plasma concentration of very long chain fatty acids (VLCFA) is inconclusive, and – The service is required as a confirmatory test for the diagnosis of adrenoleukodystrophy • ACADS (acyl-CoA dehydrogenase, C-2 to C-3 short chain), full gene sequence: <ul style="list-style-type: none"> – The patient has elevated C4-C on newborn screening test, and – Confirmation (urine acylglycines or urine organic acids) that C4 (butyrylcarnitine) and/or ethylmalonic acid (EMA) are elevated • CPOX (coproporphyrinogen oxidase), full gene sequence: <ul style="list-style-type: none"> – The patient has elevated urinary and fecal coproporphyrin III, and – The patient requires the service as a confirmatory test for hereditary coproporphyrin • CTRC (chymotrypsin C) (e.g, hereditary pancreatitis), full gene sequence: <ul style="list-style-type: none"> – The patient has an unexplained documented episode of acute pancreatitis in childhood, or 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81405</p> <p>Molecular Pathology Procedure, Level 6</p> <p><i>Continued below</i></p>	<p>Yes</p> <p><i>Continued</i></p>	<ul style="list-style-type: none"> - Recurrent acute attacks of pancreatitis of unknown cause, or - Chronic pancreatitis or possible chronic pancreatitis (ie, does not meet diagnostic criteria but clinical evidence of chronic pancreatitis is noted) of unknown cause, particularly with onset younger than 25 years of age, or - A family history of recurrent acute pancreatitis, chronic pancreatitis of unknown cause, and/or childhood pancreatitis of unknown cause consistent with autosomal dominant inheritance - Evidence of pancreatitis related disorders (male infertility or bronchiectasis) • EMD (Emery-Dreifuss muscular dystrophy) <ul style="list-style-type: none"> - The patient has clinical features suspicious for, or requires the service as a confirmatory test for Emery-Dreifuss muscular dystrophy • GDF2 (Growth/Differentiation Factor 2) <ul style="list-style-type: none"> - The member has suspected hereditary hemorrhagic telangiectasia (HHT) aka Rendu-Osler-Weber- syndrome (ICD 10 dx I78.0) with concern for mutations in GDF2 and/or RASA1 • GLA (galactosidase alpha [for example, Fabry disease]), full gene sequence: <ul style="list-style-type: none"> - The patient has a family member with documented disease-causing mutation, and 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81405 Molecular Pathology Procedure, Level 6</p> <p><i>Continued below</i></p>	<p>Yes</p> <p><i>Continued</i></p>	<ul style="list-style-type: none"> – The decision whether to initiate enzyme replacement therapy will be contingent on the results • HNF1A (HNF1 homeobox A) <ul style="list-style-type: none"> – The patient requires the service as a diagnostic test for MODY, and – Is younger than 25 years of age, and – Has a family history of diabetes, and – Has negative islet of autoantibodies • HNF1B (HNF1 homeobox B) <ul style="list-style-type: none"> – The patient requires the service as a diagnostic test for MODY, and – Is younger than 25 years of age, and – Has a family history of diabetes, and – Has negative islet of autoantibodies • LAMP2 (Danon disease) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for glycogen storage disease IIb (Danon disease) • NF2 (neurofibromatosis, type 2): <ul style="list-style-type: none"> – The patient has clinical features suspicious for, or requires the service as a confirmatory test for type 2 neurofibromatosis, OR – The patient is at high risk for neurofibromatosis with one or more of the following: <ul style="list-style-type: none"> – A first-degree relative with type 2 neurofibromatosis – Multiple spinal tumors (schwannomas, meningiomas) – Cutaneous schwannomas – Sporadic vestibular schwannoma younger than 30 years of age, or spinal 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81405</p> <p>Molecular Pathology Procedure, Level 6</p> <p><i>Continued below</i></p>	<p>Yes</p>	<p>tumor or meningioma younger than 20 years of age</p> <ul style="list-style-type: none"> • NPHS2 (steroid resistant nephrotic syndrome [SRNS]) <ul style="list-style-type: none"> – The patient has clinical diagnosis of SRNS, and – Treatment will be contingent on the test results • OTC (ornithine transcarbamylase deficiency) <ul style="list-style-type: none"> – The patient has clinical signs and symptoms of urea cycle disorders with positive biochemical laboratory results and requires the service as a confirmatory test for ornithine transcarbamylase deficiency • PKLR (pyruvate kinase, liver and RBC), full gene sequence <ul style="list-style-type: none"> – The patient has clinical features suspicious for, or requires the service as a confirmatory test for pyruvate kinase deficiency • RASA1 <ul style="list-style-type: none"> – The member has suspected hereditary hemorrhagic telangiectasia (HHT) aka Rendu-Osler-Weber- syndrome (ICD 10 dx I78.0) with concern for mutations in GDF2 and/or RASA1 • RET (multiple endocrine neoplasia [MEN], type 2A and familial medullary thyroid carcinoma [MTC]) – exons 10, 11, 13 – 16: <ul style="list-style-type: none"> – The patient has a personal history of MTC, or MEN, type 2A, or 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81405</p> <p>Molecular Pathology Procedure, Level 6</p> <p><i>Continued below</i></p>		<ul style="list-style-type: none"> – The patient has pheochromocytoma and a family history of MTC or pheochromocytoma, or – The patient has sporadic MEN2-related tumors and is younger than 35 years of age, multicentric tumors in one organ, and/or two different organs affected, or – The patient has a family history consistent with MEN, type 2A • RET (ret proto-oncogen), targeted sequence analysis: <ul style="list-style-type: none"> – The patient has a personal history of primary C cell hyperplasia, MTC, or MEN, type 2A, or – The patient has a family history consistent with MEN, type 2A or MTC, and at risk for autosomal dominant inheritance of the syndrome • SLC2A1 (glucose transporter type 1 [GLUT 1] deficiency syndrome) <ul style="list-style-type: none"> – The patient has clinical features suspicious for, or requires the service as a confirmatory test for GLUT 1 deficiency syndrome • SLC22A5 (for carnitine deficiency or carnitine uptake defect) <ul style="list-style-type: none"> – allowable when the newborn screen is positive for low carnitine levels or when there is clinical suspicion • SPRED1 (Legius syndrome) <ul style="list-style-type: none"> – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Legius syndrome • TCF4 (Pitt-Hopkins syndrome) 		

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81405</p> <p>Molecular Pathology Procedure, Level 6</p> <p><i>Continued below</i></p>		<ul style="list-style-type: none"> - The patient has clinical features suspicious for, or requires the service as a confirmatory test for Pitt-Hopkins syndrome • THRB (Thyroid Hormone Receptor, Beta) (e.g., thyroid hormone resistance, thyroid hormone beta receptor deficiency), full gene sequence or targeted sequence analysis of more than 5 exons <ul style="list-style-type: none"> - The patient has clinical presentation suspicious for Resistance to Thyroid Hormone- beta (RTH-beta) with any one of the following: <ul style="list-style-type: none"> ○ Elevated free T4 and/or free T3 with normal or mildly elevated TSH ○ Goiter or tachycardia regardless of other clinical signs and symptoms of thyroid dysfunction ○ Requiring high doses of T4 or T3 to reduce the TSH secretion or to induce the appropriate responses in peripheral tissues ○ No evidence of thyroid hormone binding abnormalities or pituitary adenoma ○ Family history of thyroid disease or RTH-beta - The test is needed to confirm the diagnosis of RTH-beta • TSC1 (tuberous sclerosis complex 1) – duplication/deletion analysis - The patient has signs or symptoms of 		

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<i>Continued from above</i>		<p>tuberous sclerosis complex but a diagnosis cannot be clinically confirmed</p> <ul style="list-style-type: none"> • WT1 (Wilms tumor 1) – full gene sequence – The patient has suspected or confirmed acute myeloid leukemia, and the result of the test will influence the diagnosis, prognosis and/or therapeutic management 		

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><u>81406</u> Molecular Pathology Procedure, Level 7 <i>Continued below</i></p>	<p>Yes</p> <p><i>Continued</i></p>	<p>Coverage for CPT-4 code 81406 (molecular pathology procedure, Level 7) is limited to the listed services. Reimbursement for code 81406 requires an approved TAR and requires providers to document one of the following on the TAR:</p> <ul style="list-style-type: none"> • ACADVL (very long chain acyl-coenzyme A dehydrogenase deficiency) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for ACADVL • AFG3L2 (spinocerebellar ataxia) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for spinocerebellar ataxia • ATP7B (Wilson disease): <ul style="list-style-type: none"> – The patient has clinical features suspicious for Wilson disease, and – Diagnosis cannot be made based on the results of biochemical testing and liver biopsy, and – The patient requires the service as a confirmatory test for Wilson disease • BTK (X-linked agammaglobulinemia): <ul style="list-style-type: none"> – Patient with a single X chromosome has clinical features suspicious for X-linked agammaglobulinemia, and – Patient with a single X chromosome has less than two percent CD19+ B cells • CDH1 (hereditary diffuse gastric cancer): <ul style="list-style-type: none"> – Two gastric cancer cases in family, one confirmed diffuse gastric cancer younger than 50 years of age, or – Three confirmed diffuse gastric cancer cases in first or second degree relatives, regardless of age, or 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
Continued from above 81406 Molecular Pathology Procedure, Level 7	Yes	<ul style="list-style-type: none"> - Diffuse gastric cancer diagnosed younger than 40 years of age, or - Personal or family history of diffuse gastric cancer and lobular breast cancer, one diagnosed younger than 50 years of age • CNTNAP2 (Pitt-Hopkins-like syndrome) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Pitt-Hopkins syndrome • DSP The patient has clinical features suspicious for Arrhythmogenic Right Ventricular Myopathy ICD 10 code I42. • GCK (glucokinase [hexokinase 4]) <ul style="list-style-type: none"> - The patient requires the service as diagnostic test for MODY, and - Is younger than 25 years of age, and - Has a family history of diabetes, and - Has negative islet of autoantibodies • GDF2 (Growth/Differentiation Factor 2) <ul style="list-style-type: none"> - The member has suspected hereditary hemorrhagic telangiectasia (HHT) aka Rendu-Osler-Weber- syndrome (ICD 10 dx I78.0) with concern for mutations in GDF2 and/or RASA1 • GLUD1 (familial hyperinsulinism): <ul style="list-style-type: none"> - The patient has persistent hyperinsulinemic hypoglycemia of infancy (PHHI) and failed medical therapy, and - The patient is under evaluation for surgical intervention • HMBS (hydroxymethylbilane synthase), full gene sequence – The patient has clinical 	Once-in-a-lifetime, any provider, except with valid TAR override	
	Continued			

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
Continued from above 81406 Molecular Pathology Procedure, Level 7 Continued below	Yes	<p>features suspicious for, or requires the service as a confirmatory test for acute intermittent porphyria</p> <ul style="list-style-type: none"> ● HNF4A (hepatocyte nuclear factor 4, alpha) <ul style="list-style-type: none"> - The patient requires the service as a diagnostic test for MODY, and - Is younger than 25 years of age, and - Has a family history of diabetes, and - Has negative islet of autoantibodies ● IDUA (iduronidase, alpha-L) (eg, mucopolysaccharidosis type I), full gene sequence. <ul style="list-style-type: none"> - The patient has clinical signs and symptoms consistent with mucopolysaccharidosis type I, and - Treatment option (allogeneic transplantation or gene therapy) will be contingent on the test results ● JAG1 (Alagille syndrome) – duplication/deletion – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Alagille syndrome ● KCNQ2 (potassium voltage-gated channel, KQT-like subfamily, member 2 [e.g. epileptic encephalopathy], full gene sequence) <ul style="list-style-type: none"> - The patient has clinical symptoms and electroencephalogram (EEG) patterns consistent with early infantile epileptic encephalopathy, and - Treatment is contingent on test results ● MUTYH (MYH-associated polyposis) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for MUTYH-associated polyposis 	Once-in-a-lifetime, any provider, except with valid TAR override	
	Continued			

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
Continued from above 81406 Molecular Pathology Procedure, Level 7 Continued below	Yes	<ul style="list-style-type: none"> ● NF2 (neurofibromatosis, type 2): <ul style="list-style-type: none"> - The patient has clinical features suspicious for, or requires the service as a confirmatory test for type 2 neurofibromatosis, or - The patient is at high risk for neurofibromatosis with one or more of the following <ul style="list-style-type: none"> ○ A first-degree relative with type 2 neurofibromatosis ○ Multiple spinal tumors (schwannomas, meningiomas) ○ Cutaneous schwannomas ○ Sporadic vestibular schwannoma younger than 30 years of age, or spinal tumor or meningioma younger than 20 years of age ● PCSK9 (proprotein convertase subtilisin/kexin type 9) (e.g., familial hypercholesterolemia), full gene sequence <ul style="list-style-type: none"> - Patient has coronary artery disease (CAD) or has risk factors for CAD - The intention to treat or not to treat with PCSK9 inhibitors will be contingent, at least in part, on the test results ● PHEX (phosphate-regulating endopeptidase homolog, X-Linked) (e.g. hypophosphatemic rickets), full gene sequence <ul style="list-style-type: none"> - The patient is undergoing evaluation for X-Linked Hypophosphatemia (XLH); and - Diagnosis was not able to be established based on biochemical testing, which included the following tests: 	Once-in-a-lifetime, any provider, except with valid TAR override	
	Continued			

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
Continued from above 81406 Molecular Pathology Procedure, Level 7 Continued below	Yes	<ul style="list-style-type: none"> - Serum calcium, phosphate and alkaline phosphatase, and - PTH, 25 hydroxyvitamin D, and 1,25 dihydroxyvitamin D, and - Urinary calcium excretion; and <p>3. The confirmation of the diagnosis and the treatment strategy is contingent on the test result.</p> <ul style="list-style-type: none"> • POLG (polymerase [DNA directed], gamma [e.g., Alpers-Huttenlocher syndrome, autosomal dominant progressive external ophthalmoplegia], full gene sequence). TAR may be approved based on one of the following numbered criteria: <ul style="list-style-type: none"> - The patient is undergoing consideration for treatment using valproic acid, or - The patient is undergoing evaluation for potentially having any one of the following conditions: <ul style="list-style-type: none"> o Alpers-Huttenlocher syndrome o Ataxia neuropathy spectrum (ANS), previously known as mitochondrial recessive ataxia syndrome (MIRAS) and sensory ataxia neuropathy, dysarthria and ophthalmoplegia (SANDO) o Autosomal dominant progressive external ophthalmoplegia o Autosomal recessive progressive external ophthalmoplegia o Childhood myocerebrohepatopathy spectrum o Myoclonic epilepsy myopathy sensory ataxia 	Once-in-a-lifetime, any provider, except with valid TAR override	
	Continued			

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81406</p> <p>Molecular Pathology Procedure, Level 7</p>	<p>Yes</p>	<ul style="list-style-type: none"> • PPOX (protoporphyrinogen oxidase), full gene sequence – The patient has clinical features suspicious for, or requires the service as a confirmatory test for acute variegate porphyria • PRKCG (spinocerebellar ataxia) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for spinocerebellar ataxia • PYGM (glycogen storage disease type V, McArdle disease) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for glycogen storage disease type V (McArdle disease) • RASA1 <ul style="list-style-type: none"> – The member has suspected hereditary hemorrhagic telangiectasia (HHT) aka Rendu-Osler-Weber- syndrome (ICD 10 dx I78.0) with concern for mutations in GDF2 and/or RASA1 • RPE65 (retinal pigment epithelium-specific protein 65kDa) <ul style="list-style-type: none"> – Patient has a clinical diagnosis of retinal dystrophy, and – The decision for gene therapy is contingent on the test results • SCNN1A (pseudohypoaldosteronism) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for pseudohypoaldosteronism • SCNN1B (Liddle syndrome, pseudohypoaldosteronism) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Liddle syndrome, pseudohypoaldosteronism 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p>81406</p> <p>Molecular Pathology Procedure, Level 7</p>		<ul style="list-style-type: none"> • SCNN1G (Liddle syndrome, pseudohypoaldosteronism) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Liddle syndrome, pseudohypoaldosteronism • SLC37A4 (glycogen storage disease, type Ib) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for glycogen storage disease, type Ib • TCF4 (Pitt-Hopkins syndrome) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Pitt-Hopkins syndrome • TSC1 (tuberous sclerosis complex 1) – full gene sequence – The patient has signs or symptoms of tuberous sclerosis complex but a diagnosis cannot be clinically confirmed • TSC2 (tuberous sclerosis complex 2) – duplication/deletion analysis – The patient has signs or symptoms of tuberous sclerosis complex but a diagnosis cannot be clinically confirmed • UMOD (glomerulocystic kidney disease with hyperuricemia and isosthenuria) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for glomerulocystic kidney disease with hyperuricemia and isosthenuria • WAS (Wiskott-Aldrich syndrome) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Wiskott-Aldrich syndrome 		

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81407</u> Molecular Pathology Procedure, Level 8 <i>Continued below</i>	Yes	Coverage for CPT-4 code 81407 (molecular pathology procedure, Level 8) is limited to the listed services. Reimbursement for code 81407 requires an approved TAR and requires providers to document one of the following on the TAR: <ul style="list-style-type: none"> • ABCC8 (familial hyperinsulinism): <ul style="list-style-type: none"> – The patient has persistent hyperinsulinemic hypoglycemia of infancy (PHHI) who failed medical therapy, and – The patient is under evaluation for surgical intervention • AGL (glycogen storage disease type III) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for glycogen storage disease type III 	Once-in-a-lifetime, any provider, except with valid TAR override	
	<i>Continued</i>			

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><u>81407</u> Molecular Pathology Procedure, Level 8</p>	<p>Yes</p>	<ul style="list-style-type: none"> • JAG1 (Alagille syndrome) – full gene sequence – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Alagille syndrome • NOTCH (notch 1) – full gene sequence – The patient has suspected or confirmed acute lymphoblastic leukemia, and the result of the test will influence the diagnosis, prognosis and/or therapeutic management • NPHS1 (congenital Finnish nephrosis) – The patient has clinical diagnosis of steroid-resistant nephritic syndrome (SRNS)/congenital Finnish nephrosis, and – Treatment will be contingent on the test results • SCN1A – The patient has clinical features suspicious for, or requires the service as a confirmatory test for Dravet syndrome • SPTBN2 (spinocerebellar ataxia) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for spinocerebellar ataxia • TSC2 (tuberous sclerosis complex 2) – full gene sequence – The patient has signs or symptoms of tuberous sclerosis complex but a diagnosis cannot be clinically confirmed 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><u>81408</u> Molecular Pathology Procedure, Level 9</p>	<p>Yes</p>	<p>Coverage for CPT-4 code 81408 (molecular pathology procedure, Level 9) is limited to the listed services. Reimbursement for code 81408 requires an approved Treatment Authorization Request (TAR) explaining that the following criteria have been met:</p> <ul style="list-style-type: none"> • COL1A1, COL1A2 (Osteogenesis Imperfecta) ICD 10 code: Q78 • ITPR1 (spinocerebellar ataxia) – The patient has clinical features suspicious for, or requires the service as a confirmatory test for spinocerebellar ataxia • DMD (dystrophin), full gene analysis <ul style="list-style-type: none"> – Patient has a clinical diagnosis of dystrophinopathy based on the history, physical examination and elevated creatine kinase (CK) level – Result of the DMD (dystrophin) deletion or duplication is negative • NF1 (neurofibromatosis 1) <ul style="list-style-type: none"> – The patient has clinical features suspicious for NF1 and requires genetic testing to confirm the diagnosis (one or more signs of NF 1 present, but not enough to make clinical diagnosis), OR – Asymptomatic individual with a first, second, or third-degree relative with established diagnosis of NF1. 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	<p>First degree relatives are biological parents, siblings, and children. Second-degree relatives are biological grandparents, aunts, uncles, nephews, nieces, grandchildren and half-siblings.</p> <p>Where third degree blood relatives are mentioned, they include great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.</p>

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81412</u> Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least nine genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1	Yes	A TAR requires documentation of the following criteria: <ul style="list-style-type: none"> • Patient is considering pregnancy or is currently pregnant, and • Patient reports they are of Ashkenazi Jewish descent (family history with one Ashkenazi Jewish grandparent or more, or more immediate family members), and • The panel includes only the conditions specified by American College of Obstetricians and Gynecologists (ACOG) (e.g., [ACOG] Carrier Screening for Genetic Conditions) and/or by American College of Medical Genetics and Genomics [ACMG] for individuals of Ashkenazi Jewish descent 	Once-in-a-lifetime, any provider, except with valid TAR override	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><u>81413</u> Cardiac Ion Channelopathies genomic sequence analysis panel, must include sequencing of at least 10 genes</p>	<p>Yes</p>	<p>Reimbursement for CPT-4 code 81413 must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A.</p> <p>The required 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"> 1. Torsade de pointes in the absence of drugs known to prolong QT interval 2. T-wave alternans 3. Notched T-wave in three leads 4. Syncope 5. Family members with long QT syndrome 6. Sudden death in family members less than 30 years of age without defined cause 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	
<p><u>81414</u> Cardiac ion channelopathies; genomic sequence analysis panel, must include sequencing of at least 2 genes</p>	<p>Yes</p>	<p>Reimbursement for CPT-4 code 81414 must include sequencing of at least 2 genes, including KCNH2 and KCNQ1.</p> <p>The required 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"> 1. Torsade de pointes in the absence of drugs known to prolong QT interval 2. T-wave alternans 3. Notched T-wave in three leads 4. Syncope 5. Family members with long QT syndrome 6. Sudden death in family members less than 30 years of age without defined cause 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81419</u> 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, SLC9AG, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2	Yes	The required TAR must document the following: <ul style="list-style-type: none"> • Patient has specific epilepsy syndrome of unknown cause for which a number of genetic etiologies exist. • The test is needed for identifying the underlying diagnosis • The diagnostic or treatment strategy will be contingent on test results 	N/A	
<u>81420</u> Fetal chromosomal aneuploidy genomic sequence analysis panel, must include analysis of chromosomes 13, 18, and 21	No	N/A	Payable no more than once per pregnancy	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.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><u>81432</u> Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes</p> <p><i>Continued below</i></p>	<p>Yes</p>	<p>A TAR with documentation of one or more the following criteria is required:</p> <ol style="list-style-type: none"> 1. An individual from a family member with a known deleterious BRCA mutation; or 2. Personal history of breast cancer (invasive or ductal carcinoma in situ) plus one of more of the following: <ul style="list-style-type: none"> • Diagnosed at ≤ 45 years of age, or • Diagnosed at 46 – 50 years of age with: <ul style="list-style-type: none"> – An additional breast cancer primary at any age – One or more close blood relatives with breast cancer at any age – One or more close blood relatives with prostate cancer (Gleason score ≥ 7) – An unknown or limited family history; or • Diagnosed at ≤ 60 years of age with a triple negative breast cancer; or • Diagnosed at any age with: <ul style="list-style-type: none"> – One or more close relatives with: <ul style="list-style-type: none"> ❖ Breast cancer diagnosed at ≤ 50 years of age; ❖ Ovarian carcinoma; or ❖ Male Breast cancer; or ❖ Metastatic prostate cancer; or ❖ Pancreatic cancer – Two or more additional diagnosis of breast cancer at any age in patient and/or in close blood relatives; or – Ashkenazi Jewish ancestry; or 3. Personal history of ovarian carcinoma (includes fallopian tube and primary peritoneal cancers); or 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Continued from above</i></p> <p><u>81432</u></p> <p>Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes</p>		<ol style="list-style-type: none"> 4. Personal history of male breast cancer; or 5. Personal history of pancreatic cancer, or 6. Personal history of metastatic prostate cancer (biopsy-proven and/or with radiographic evidence; includes distant metastasis and regional bed or nodes; not biochemical recurrence); or 7. Personal history of high-grade prostate cancer (Gleason score ≥ 7) at any age with: <ul style="list-style-type: none"> • One or more close blood relatives (first, second or third-degree) with ovarian carcinoma, pancreatic cancer or metastatic prostate cancer at any age or breast cancer under 50 years of age; or • Two or more close blood relatives (first, second, or third-degree relatives on the same side of family) with breast or prostate cancer (any grade) at any age; or • Ashkenazi Jewish ancestry; or 8. BRCA1/2 pathogenic/likely pathogenic variant detected by tumor profiling on any tumor type in the absence of germline pathogenic/likely pathogenic variant analysis; or 9. For an individual without history of breast or ovarian cancer, but with one or more first or second-degree blood relative meeting any of the above criteria 		

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81434</u> Hereditary retinal disorders (e.g., retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR and USH2A	Yes	A TAR is required with the following documentation: <ul style="list-style-type: none"> • Patient has a clinical diagnosis of retinal dystrophy (retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy) <u>and</u> • The decision for gene therapy is contingent on the test results 	Once-in-a-lifetime, any provider, except with valid TAR override	
<u>81435</u> Hereditary Colon Cancer Disorders; Genomic sequence analysis panel, must include sequencing of at least 10 genes	No	Reimbursement for CPT-4 code 81435 must include analysis of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4 and STK11. Reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030 - Z85.038, Z85.040 - Z85.048, Z85.42, Z86.010	Once-in-a-lifetime, any provider, except with valid TAR override	
<u>81436</u> Hereditary colon cancer disorders; genomic sequence analysis panel, must include sequencing of at least 5 genes	No	Reimbursement for CPT-4 code 81436 must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11. Reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: C17.0 – C20, C24.0 – C25.9, C54.0 – C54.9, C65.1 – C66.9, C71.0 – C71.9, D23.0 – D23.9, Z80.0, Z80.49, Z85.030 – Z85.038, Z85.040 – Z85.048, Z85.42 or Z86.010	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81439</u> Inherited Cardiomyopathy Genomic sequence analysis panel, must include sequencing of at least 5 genes	No	Reimbursement for CPT-4 code 81439 must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN. Reimbursable only when billed in conjunction with ICD-10-CM diagnosis codes: I42.0 – I42.5 or Z82.41 – Z82.49. A TAR may override the frequency limit and required ICD-10-CM diagnosis codes.	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81445 Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5 to 50 genes	Yes	<p>A TAR for CPT code 81445 requires documentation of the following criteria:</p> <ul style="list-style-type: none"> • For Somatic Testing: <ul style="list-style-type: none"> – The patient has either recurrent, relapsed, refractory, metastatic or advanced stages III or IV cancer, and – 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 – The decision for additional cancer treatment is contingent on the test results. • For Germline Testing: <ul style="list-style-type: none"> – Ovarian or breast cancer, and – Clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer (i.e., American College of Obstetrician Gynecologists' criteria for further genetic evaluation for hereditary [germline] breast and ovarian cancer), and – A risk factor for germline (inherited) breast or ovarian cancer, and (BRCA1/2, Myriad, Claus, Boadicea, or Tyrer Cuzick), and – Has not been previously tested with the same germline test using NGS for the same germline genetic content. • Independent of the above criteria, either Somatic or Germline 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. 	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81448</u> Hereditary peripheral neuropathies, genomic sequence analysis panel, must include sequencing of at least 5 neuropathy-related genes	No	One of the following ICD-10-CM codes is required on the claim (except with valid TAR): G11.4, G60.0	Once-in-a-lifetime, any provider, except with valid TAR override	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81455 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET),</p>	<p>Yes</p>	<p>A TAR for CPT code 81455 requires documentation of the following criteria: For Somatic Testing:</p> <ul style="list-style-type: none"> • The patient has either recurrent, relapsed, refractory, metastatic or advanced stages III or IV cancer, and • 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 • The decision for additional cancer treatment is contingent on the test results. <p>For Germline Testing:</p> <ul style="list-style-type: none"> • Ovarian or breast cancer, and • Clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer (i.e., American College of Obstetrician Gynecologists' criteria for further genetic evaluation for hereditary [germline] breast and ovarian cancer), and • A risk factor for germline (inherited) breast or ovarian cancer, and (BRCA1, BRCA2, MYRIAD, CLAU, BOADICEA, or TYRER-CUZICK), and • Has not been previously tested with the same germline test using NGS for the same germline genetic content. <p>Independent of the above criteria, either Somatic or Germline testing may be approved if the test is FDA-approved as a Companion Diagnostic Device, and the decision for additional treatment is contingent on the test results.</p>	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81457 Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability</p>	<p>Yes</p>	<p>A TAR for CPT code 81457 requires documentation of the following criteria:</p> <p><u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and • 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 • The decision for additional cancer treatment is contingent on the test results. <p><u>For Germline Testing</u></p> <ul style="list-style-type: none"> • The patient has ovarian or breast cancer, and • The patient has a clinical indication for germline (inherited) testing for inherited breast or ovarian cancer, and • The patient has a risk factor for germline (inherited) breast or ovarian cancer, and • The patient has not been previously tested with the same germline test using NGS for the same germline genetic content. <p>Independent of the above criteria, either Somatic or Germline 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, any provider, except with valid TAR override</p>	<p>NCCN guideline recommendations will be reviewed for medical necessity</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81458 Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability</p>	<p>Yes</p>	<p>A TAR for CPT code 81458 requires documentation of the following criteria:</p> <p><u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and • 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 • The decision for additional cancer treatment is contingent on the test results. <p><u>For Germline Testing</u></p> <ul style="list-style-type: none"> • The patient has ovarian or breast cancer, and • The patient has a clinical indication for germline (inherited) testing for inherited breast or ovarian cancer, and • The patient has a risk factor for germline (inherited) breast or ovarian cancer, and • The patient has not been previously tested with the same germline test using NGS for the same germline genetic content. <p>Independent of the above criteria, either Somatic or Germline 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, any provider, except with valid TAR override</p>	<p>NCCN guideline recommendations will be reviewed for medical necessity</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81459 Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements</p>	<p>Yes</p>	<p>A TAR for CPT code 81459 requires documentation of the following criteria:</p> <p><u>For Somatic Testing</u></p> <ul style="list-style-type: none"> • The patient has recurrent, relapsed, refractory, metastatic or advanced stage III or IV cancer, and • 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 • The decision for additional cancer treatment is contingent on the test results. <p><u>For Germline Testing</u></p> <ul style="list-style-type: none"> • The patient has ovarian or breast cancer, and • The patient has a clinical indication for germline (inherited) testing for inherited breast or ovarian cancer, and • The patient has a risk factor for germline (inherited) breast or ovarian cancer, and • The patient has not been previously tested with the same germline test using NGS for the same germline genetic content. <p>Independent of the above criteria, either Somatic or Germline 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, any provider, except with valid TAR override</p>	<p>NCCN guideline recommendations will be reviewed for medical necessity</p> <p>As per APL 22-010 Cancer Biomarker Testing (06/22/2022), no prior authorization is required for cancer biomarker testing for members with advanced or metastatic stage 3 or 4 cancer for whom an FDA approved treatment is considered. The intent is to remove barriers for members with late-stage cancer. Although no prior authorization is required, a prepayment review after the service has been provided may review the submitted documents to ensure that the records reflect advanced or metastatic stage 3 or 4 cancer.</p>

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81462</u> Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (e.g., plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements	Yes	A TAR for CPT code 81462 requires documentation of the following criteria: 1. The patient has a diagnosis of non-small cell lung cancer, and 2. The patient is medically unable to undergo invasive biopsy or tumor tissue testing is not feasible, and 3. Management is contingent on the test results	Once-in-a-lifetime, any provider, except with valid TAR override	
<u>81479</u> Unlisted Molecular Pathology Procedure	Yes	Specific service being requested under this code must be defined and clinical documentation must be included for diagnosis and treatment recommendation.	N/A	Frequency will be determined by the clinical information submitted.
<u>81500</u> Oncology (ovarian), biochemical assays of two proteins	No	Reimbursable for members who meet the following criteria: <ul style="list-style-type: none"> • 18 years of age or older • Ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist ICD-10-CM diagnosis code R19.09 is required for reimbursement	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81503</u> Oncology (ovarian), biochemical assays of five proteins	No	Reimbursable for members who meet the following criteria: <ul style="list-style-type: none"> • 18 years of age or older • Ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist <p>CPT code 81503 is reimbursable only when billed in conjunction with at least one of the following ICD-10-CM diagnosis codes: D39.10 – D39.12, N83.00 – N83.02, N83.10 – N83.12, N83.201, N83.202, N83.209, N83.291, N83.292, N83.299, R19.00, R19.03 – R19.05, R19.07 or R19.09.</p>	N/A	
<u>81507</u> Fetal aneuploidy (trisomy 21, 18 and 13) DNA sequence analysis of selected regions	No	N/A	Payable no more than once per pregnancy	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.
<u>81508</u> Fetal congenital abnormalities, biochemical assays of two proteins	No	Reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: O09.00 – O09.73, Z34.00 – Z34.93, Z36.0, Z36.81, or Z36.83 – Z36.89. Reimbursable in pregnancy only.	N/A	
<u>81509</u> Fetal congenital abnormalities, biochemical assays of three proteins	No	Reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: O09.00 – O09.73, Z34.00 – Z34.93, Z36.0, Z36.81, or Z36.83 – Z36.89. Reimbursable in pregnancy only.	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81510</u> Fetal congenital abnormalities, biochemical assays of three analytes	No	Reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: O09.00 – O09.73, Z34.00 – Z34.93, Z36.0, Z36.81, or Z36.83 – Z36.89. Reimbursable in pregnancy only.	N/A	
<u>81511</u> Fetal congenital abnormalities, biochemical assays of four analytes	No	Reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: O09.00 – O09.73, Z34.00 – Z34.93, Z36.0, Z36.81, or Z36.83 – Z36.89. Reimbursable in pregnancy only.	N/A	
<u>81512</u> Fetal congenital abnormalities, biochemical assays of five analytes	No	Reimbursable only when billed in conjunction with one of the following ICD-10-CM diagnosis codes: O09.00 – O09.73, Z34.00 – Z34.93, Z36.0, Z36.81, or Z36.83 – Z36.89. Reimbursable in pregnancy only.	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>81517</u> 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	No	N/A	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81518+ Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes +See note at the end of this table	Yes	Requires a <i>Treatment Authorization Request</i> (TAR) with documentation of the following criteria: <ul style="list-style-type: none"> • The recipient is estrogen and/or progesterone receptor (ER/PgR)-positive. • The recipient is HER2-receptor negative. • The recipient is lymph node negative or lymph node positive with up to three positive nodes. • The recipient has stage I or stage II breast cancer. • The recipient is disease-free (or no evidence of metastasis). • Test results will be used in determining treatment management of the patient for chemotherapy and/or extended endocrine therapy. Use CPT code 81518 when billing for Breast Cancer Index.	Once-in-a-lifetime +See note at the end of this table	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81519+ Oncology (breast), mRNA, gene expression profiling by real time RT-PCR of 21 genes</p> <p>+See note at the end of this table</p>	<p>Yes</p>	<p>Requires a TAR with documentation of the following criteria:</p> <ul style="list-style-type: none"> • The recipient is estrogen and progesterone receptor (ER/PgR)-positive. • The recipient is HER2-receptor negative. • The recipient is premenopausal and lymph node negative or has 1-3 positive lymph nodes (no distant metastasis) • OR when the recipient is post-menopausal 0 - 3 positive lymph nodes(no distant metastasis) • The recipient has stage I or stage II breast cancer. • The recipient is a candidate for chemotherapy. • The assay is used within six months of diagnosis. • The recipient is under consideration for adjuvant systemic therapy. <p>Use CPT code 81519 when billing for Oncotype Dx.</p>	<p>Once-in-a-lifetime</p> <p>+See note at the end of this table</p>	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81520+ Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes</p> <p>+See note at the end of this table</p>	<p>Yes</p>	<p>Requires a TAR with documentation of the following criteria:</p> <ul style="list-style-type: none"> • The recipient is estrogen and progesterone receptor (ER/PgR)-positive. • The recipient is HER2-receptor negative. • The recipient is lymph node negative. • The recipient has stage I or stage II breast cancer. • The recipient is a candidate for chemotherapy. • The assay is used within six months of diagnosis. • The recipient is under consideration for adjuvant systemic therapy. <p>Use CPT code 81520 when billing for Prosigna.</p>	<p>Once-in-a-lifetime +See note at the end of this table</p>	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81521+ Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes</p> <p>+See note at the end of this table</p>	<p>Yes</p>	<p>Requires a TAR with documentation of the following criteria:</p> <ul style="list-style-type: none"> • The recipient has high clinical risk per MINDACT categorization. • The recipient is estrogen and progesterone receptor (ER/PgR)-positive. • The recipient is HER2-receptor negative. • The recipient is lymph node negative or lymph node positive. • The recipient is a candidate for chemotherapy. • The assay is used within six months of diagnosis. • The recipient is under consideration for adjuvant systemic therapy. <p>Use CPT code 81521 when billing for MammaPrint.</p> <p>As noted in the 2017 ASCO guideline, the Adjuvant! Online website was not functional. As an alternative, clinicians can determine a patient's clinical risk status by using the printed version of the Adjuvant! Online clinical risk criteria found in the Data Supplement of the MINDACT publication.</p>	<p>Once-in-a-lifetime</p> <p>+See note at the end of this table</p>	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81522+ Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes</p> <p>+See note at the end of this table</p>	<p>Yes</p>	<p>Requires a TAR with documentation of the following criteria:</p> <ul style="list-style-type: none"> • The recipient is estrogen and progesterone receptor (ER/PgR)-positive. • The recipient is HER2-receptor negative. • The recipient is lymph node negative. • The recipient has stage I or stage II breast cancer. • The recipient is a candidate for chemotherapy. • The assay is used within six months of diagnosis. • The recipient is under consideration for adjuvant systemic therapy. <p>Use CPT 81522 when billing for EndoPredict.</p>	<p>Once-in-a-lifetime +See note at the end of this table</p>	

MCUP3131- A Genetic Testing Requirements: Providers should refer to the CPT or HCPCS code book, as appropriate, for full descriptions of codes.

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p>81523+</p> <p>Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis</p> <p>+See note at the end of this table</p>	No	<p>For reference, here are the criteria outlined by DHCS:</p> <ul style="list-style-type: none"> • The recipient has high clinical risk per MINDACT categorization. • The recipient is estrogen and progesterone receptor (ER/PgR)-positive. • The recipient is HER2- receptor negative. • The recipient is lymph node negative or lymph node positive. • The recipient is a candidate for chemotherapy. • The assay is used within six months of diagnosis. • The recipient is under consideration for adjuvant systemic therapy. <p>Use CPT code 81523 when billing for MammaPrint. As noted in the 2017 ASCO guideline, the Adjuvant! Online website was not functional.</p> <p>As an alternative, clinicians can determine a patient's clinical risk status by using the printed version of the Adjuvant! Online clinical risk criteria found in the Data Supplement of the MINDACT publication.</p>	Once in a lifetime	
<p><u>81528</u></p> <p>Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers</p>	No	<p>Reimbursable for recipients 45 – 75 years of age. For recipients outside this age range, providers must submit a TAR documenting medical necessity.</p> <p>* For recipients requiring additional tests within a year, providers must submit a TAR documenting medical necessity.</p>	No more than once every two years *	

CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><u>81541</u> oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score</p> <p><i>Cont'd</i></p>	<p>Yes</p>	<p>The following criteria must be documented on the TAR:</p> <ol style="list-style-type: none"> 1. For identification of patients with Prostate Cancer who are most likely to benefit from active surveillance or treatment. <ul style="list-style-type: none"> • Coverage is limited to Decipher®, Prolaris® and ProMark. Gene expression profiling for prostate cancer may be billed as follows: <ul style="list-style-type: none"> – Decipher® Prostate – Use CPT code 81542 – Prolaris® – Use CPT code 81541 – ProMark – Use CPT code 81599 • The patient must have one of the following: <ul style="list-style-type: none"> – Higher volume Grade Group 1 – Favorable intermediate risk (e.g., Grade Group 2, percentage of positive biopsy scores, 50 percent and no more than on NCCN intermediate-risk factor) – Discordant features in their risk stratification (e.g., palpable mass with Grade Group 1) – Other features associated with progression while on active surveillance (e.g., high PSA density and certain germline or somatic mutations) – Unfavorable intermediate-risk when considering decisions to proceed with treatment (i.e. add androgen deprivation therapy to radiation) • Result of the test, when considered as a whole with routine clinical factors, is 	<p>Once-in-a-lifetime, any provider, except with valid TAR override</p>	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<p><i>Cont'd from above</i></p> <p><u>81541</u> oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score</p>		<p>likely to influence the decision to proceed with surveillance or treatment</p> <p>2. For post-prostatectomy patients who seek guidance on adjuvant vs. salvage radiation:</p> <ul style="list-style-type: none"> • Coverage is limited to Decipher Genomic Classifier • Result of the test, when considered as a whole with routine clinical factors, is likely to affect treatment 		
<p><u>81542</u> oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score</p>	Yes	See CPT code 81541 for TAR criteria and billing requirements.	Once-in-a-lifetime, any provider, except with valid TAR override	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
81546 Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	Yes	The following numbered criteria must be documented on the TAR: <ol style="list-style-type: none"> 1. The patient is under evaluation for thyroid nodule(s) 2. The cytopathology result from fine needle aspiration is indeterminate, defined as one of the following: <ul style="list-style-type: none"> • Follicular lesion of undetermined significance (FLUS), Bethesda III, or • Atypia of undetermined significance (AUS), Bethesda III, or • Follicular neoplasm, Bethesda IV. 3. The diagnostic or treatment strategy will be contingent on test results 	N/A	
<u>81552</u> Oncology (uveal melanoma), mRNA, gene expression profiling by real -time RT-PCR of 15 genes	No	An ICD-10-CD diagnosis code from the following ranges must be documented: C69.30 – C69.32 or C69.40 – C69.42	Once-in-a-lifetime, any provider, except with valid TAR override	
<u>81596</u> Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays	No	The following ICD-10-CM code is required on the claim (except with valid TAR): B18.2	N/A	

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CPT Code Description	PHC TAR Required	TAR and/or Billing Requirements	Frequency Limit	BENEFIT COMMENTS
<u>88261 – 88269</u> <u>88280</u> Karyotype (aka Cytogenetic Studies)	No	<p>Karyotype testing for codes 88261-3 may be ordered once in a lifetime in children with phenotype of syndrome most commonly associated with a chromosomal abnormality.</p> <p>For perinatal indication, see Medi-Cal guidelines in the Genetic Counseling and Screening section gene coun 2.</p>	Once-in-a-lifetime, any provider, except with valid TAR override	

+Note:

These benefits are limited to EndoPredict, Oncotype Dx, Prosigna (PAM50 risk of recurrence score) and Breast Cancer Index.

Use CPT code 81518 when billing for Breast Cancer Index.

Use CPT code 81519 when billing for Oncotype Dx.

Use CPT code 81520 when billing for Prosigna.

Use CPT code 81521 when billing for MammaPrint.

Use CPT code 81522 when billing for EndoPredict.

These once-in-a-lifetime benefits may be billed for the same recipient and any provider. Providers need an approved TAR and documentation showing that the recipient has a new second primary breast cancer that meets the necessary criteria as listed above to override the once-in-a-lifetime frequency.

Concurrent use of more than one test is not recommended as there is no data to support that ordering multiple assays in an individual patient would be beneficial in guiding treatment decisions.