Beneficiary Full Name: _____ Sponsor's SSN: _____ - _____ - _____

Date of Birth: _____ Beneficiary State of Residence: _____

Dear Provider,

Please complete and sign this **Laboratory Developed Test (LDT) Letter of Attestation** and return as indicated on the additional information request letter or attach it to your online request. TRICARE Operations Manual, Chapter 18, allows coverage for LDTs when specific coverage criteria are met.

SECTION I – Laboratory developed tests that may be considered for coverage under the Defense Health Agency (DHA) Evaluation of Non-United States (U.S.) Food and Drug Administration (FDA) Approved LDT Demonstration Project. (If the requested test is not indicated in Section I, please complete Section II.)

DIRECTIONS: Mark the single gene(s) test(s) being requested below in COLUMN I, mark the indication for the test in COLUMN II, and write the Current Procedural Terminology (CPT®) code(s) and quantity in COLUMN III being requested.

For panel tests: Mark all the genes in Column 1 that are within the panel test AND select the indication for those genes in Column II. (You do not need to complete Column III.)

Failure to complete the form in its entirety will result in a delay in processing your request.

Patient Medical History

Has the patient had the requested test previously? ☐ Yes ☐ No If "Yes," explain medical necessity for repeat testing:

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
Afirma® Thyroid FNA Analysis	☐ To aid in thyroid nodule diagnosis by reducing unnecessary surgeries in patients with indeterminate thyroid nodules ☐ Other indication		
ALK	☐ To determine response to tyrosine kinase inhibitor (TKI) therapy in patients with adenocarcinoma of the lung or mixed lung cancer with adenocarcinoma component of the lung ☐ Other indication		
APC	☐ Testing for APC variants in individuals with clinical symptoms consistent with familial adenomatous polyposis (FAP) ☐ Testing for APC variants in individuals with clinical symptoms consistent with attenuated familial adenomatous polyposis (AFAP) ☐ Testing for APC variants in individuals with clinical symptoms consistent with Turcot's or Gardner's syndromes ☐ Testing individuals with an APC-associated polyposis syndrome for the purpose of identifying a variant that may be used to screen at-risk relatives ☐ For the presymptomatic testing of at-risk relatives for a known familial variant ☐ Other indication		
ATXN1	☐ Diagnosis of spinocerebellar ataxia type 1 (SCA1) in patients with cerebellar ataxia of unknown etiology, along with extracerebellar symptoms associated with SCA1 and/or a family history consistent with autosomal dominant inheritance ☐ Diagnosis of SCA1 in symptomatic family members of known SCA1 patients ☐ Other indication		
ATXN2	☐ Diagnosis of spinocerebellar ataxia type 2 (SCA2) in patients with cerebellar ataxia of unknown etiology, along with extracerebellar symptoms associated with SCA2 and/or a family history consistent with autosomal dominant inheritance ☐ Diagnosis of SCA2 in symptomatic family members of known SCA2 patients ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
ATXN3	☐ Diagnosis of spinocerebellar ataxia type 3 (SCA3) in patients with cerebellar ataxia of unknown etiology, along with extracerebellar symptoms associated with SCA3 and/or a family history consistent with autosomal dominant inheritance ☐ Diagnosis of SCA3 in symptomatic family members of known SCA3 patients ☐ Other indication		
ATXN7	☐ Diagnosis of spinocerebellar ataxia type 7 (SCA7) in patients with cerebellar ataxia and visual disturbance ☐ Diagnosis of SCA7 in symptomatic family members of known SCA7 patients ☐ Other indication		
ATXN10	☐ Diagnosis of spinocerebellar ataxia type 10 (SCA10) in ataxia patients whose ancestry is of American Indian origin, and whose family history is consistent with autosomal dominant inheritance ☐ Diagnosis of SCA10 in symptomatic family members of known SCA10 patients ☐ Other indication		
BCR/ABL1	☐ Diagnostic assessment of individuals with suspected chronic myelogenous leukemia (CML) by quantitative RT-PCR (RQ-PCR) ☐ Diagnostic assessment of individuals with suspected CML by qualitative RT-PCR ☐ Monitoring response to tyrosine kinase inhibitor (TKI) therapy, such as imatinib, in individuals with CML by RQ-PCR ☐ Testing for the presence of the BCR/ABL1 p.Thr315Ile variant in CML patients to guide treatment selection following resistance to first-line imatinib therapy ☐ Testing for the presence of BCR/ABL1 variants other than p.Thr315Ile in CML patients to guide treatment selection following resistance to first-line imatinib therapy ☐ Other indication		
Biotheranostics Breast Cancer Index®	☐ Women with diagnosed early stage hormone-receptor positive (HR+), lymph node-negative (LN-) breast cancer being treated with adjuvant endocrine therapy ☐ Women with diagnosed early stage hormone-receptor positive (HR+), lymph node-positive (LN+) (1-3 nodes) breast cancer being treated with adjuvant endocrine therapy ☐ Other indication		
BMPR1A	☐ To clarify the diagnosis of individuals with juvenile polyposis syndrome (JPS) ☐ If a known SMAD4 mutation is in the family, genetic testing should be performed in the first six months of life due to hereditary hemorrhagic telangiectasia risk ☐ Other indication		
BRAF	☐ To predict response to vemurafenib therapy in patients with a positive cobas® 4800 BRAF mutation test result ☐ To predict response to trametinib monotherapy in advanced melanoma patients with a positive BRAF p.Val600Glu and/or p.Val600Lys test result ☐ To predict response to dabrafenib monotherapy in advanced melanoma patients with a positive BRAF p.Val600Glu test result ☐ To predict response to trametinib and dabrafenib combination therapy in advanced melanoma patients with a positive BRAF p.Val600Glu and/or p.Val600Lys test result ☐ For individuals with indeterminate thyroid fine-needle aspiration (FNA) biopsy cytology for diagnosis of papillary thyroid carcinoma ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
BRCA1/BRCA2 or BRACAnalysis CDx®	☐ BRCA1/BRCA2 gene testing must be in accordance with the most current National Comprehensive Cancer Network (NCCN) guidelines for breast cancer ☐ Other indication		
CACNA1A	☐ Diagnosis of spinocerebellar ataxia type 6 (SCA6) in patients with cerebellar ataxia with dysarthria and/or nystagmus ☐ Diagnosis of SCA6 in symptomatic family members of known SCA6 patients ☐ Other indication		
CALM1, CASQ2, RYR2, and/or TRDN	☐ To confirm a diagnosis of catecholaminergic polymorphic ventricular tachycardia (CPVT) in patients with clinically diagnosed or suspected CPVT ☐ Other indication		
CDH1	☐ For large rearrangements in the CDH1 gene for the treatment of hereditary diffuse gastric cancer (HDGC) ☐ Other indication		
CEBPA	☐ To guide the treatment decisions for individuals with acute myeloid leukemia (AML) ☐ Other indication		
CFTR/Cystic Fibrosis Testing	☐ Confirmation of diagnosis in individuals showing clinical symptoms of cystic fibrosis (CF) or having a high sweat chloride level ☐ Identification of newborns who are affected with CF ☐ Identification of individuals with the p.Gly551Asp variant who will respond to treatment with ivacaftor ☐ Male infertility testing and treatment **Note:** Effective Dec. 27, 2021, TRICARE covers CFTR gene testing as a preconception and prenatal carrier screening under the TRICARE basic benefit. Preconception and prenatal carrier screening for CFTR is no longer covered under the LDT Demonstration Project. Refer to TPM, Chapter 6, Section 3.2 for details. ☐ Other indication		
Chimerism Analysis	☐ For the management and treatment of stem cell transplant patients ☐ Other indication		
Chromosome 22q11.2	☐ Confirmation of diagnosis in an individual suspected of chromosome 22q11.2 deletion syndrome based on clinical findings ☐ Other indication		
COL1A1/COL1A2	☐ For sequence variants in the COL1A1/COL1A2 genes for the diagnosis of osteogenesis imperfecta (OI) when clinical and radiological examination and family history provide inadequate information for diagnosis of OI ☐ Other indication		
COL3A1	☐ To confirm or establish a diagnosis of Ehlers-Danlos syndrome type 4 (EDS IV), also known as vascular EDS, in patients with clinical symptoms or features of EDS IV ☐ Other indication		
CYP2C9	☐ For the initiation and management of warfarin treatment ☐ Other indication		
CYP2C19	☐ To manage dosing of clopidogrel ☐ Other indication		
Cytogenomic Constitutional Microarray Analysis	☐ Diagnostic evaluation of patients suspected of having a genetic syndrome (in other words, have congenital anomalies, dysmorphic features, developmental delay and/or intellectual disability) ☐ Diagnostic evaluation of individuals with autism spectrum disorder (ASD), including autism, Asperger's syndrome and pervasive developmental disorder ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
DAZ/SRY	☐ To detect submicroscopic deletions involving the Y chromosome in the evaluation of men with infertility secondary to azoospermia, oligozoospermia or teratozoospermia ☐ Other indication		
DermTech Pigmented Lesion Assay (PLA)	☐ Neoplasms of uncertain behavior of skin ☐ Other indication		
DMD	☐ For diagnostic DMD testing (deletion and duplication analysis with reflex to complete gene sequencing) in males or females exhibiting symptoms of Duchenne muscular dystrophy or Becker muscular dystrophy ☐ Other indication		
DMPK	☐ Confirmation of a diagnosis of myotonic dystrophy type 1 (DM1) or type 2 (DM2) in symptomatic patients ☐ Diagnosis of DM1 or DM2 in asymptomatic adults who are at an increased risk of DM1 or DM2 through a positive family history ☐ Other indication		
DSC2, DSG2, DSP, JUP, PKP2, RYR2, TGFB3, and/or TMEM43	☐ For sequence variants in the DSC2, DSG2, DSP, JUP, PKP2, RYR2, TGFB3, and TMEM43 genes to confirm a diagnosis of arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) in probands ☐ For a known familial sequence variant in the DSC2, DSG2, DSP, PKP2, or TMEM43 gene for at-risk relatives of probands with International Task Force (ITF)-confirmed ARVD/C to confirm a diagnosis of ARVD/C in those whose symptoms meet the ITF diagnostic criteria ☐ Other indication		
DYT1/TOR1A	☐ For genetic testing for sequence variants of DYT1 for patients with primary dystonia with onset < 30 years of age ☐ For genetic testing for sequence variants of DYT1 for patients with primary dystonia with onset ≥ 30 years of age who have a relative who developed dystonia aged < 30 years ☐ Other indication		
EGFR	☐ To help guide administration of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKI) in the first-line treatment of non-small cell lung cancer ☐ Other indication		
F2	**Prothrombin (factor II) related thrombophilia gene testing:** ☐ Diagnostic evaluation of individuals with a prior venous thromboembolism (VTE) during pregnancy or puerperium ☐ For patients with VTE with a personal or family history of recurrent VTE (more than two in the same person) ☐ For patients with their first VTE before age 50 with no precipitating factors ☐ For venous thrombosis at unusual sites such as the cerebral, mesenteric, portal, or hepatic veins ☐ For VTE associated with the use of estrogen-containing oral contraceptives, selective estrogen receptor modulators (SERMs), or hormone replacement therapy (HRT) ☐ To diagnose an inherited thrombophilia in female family members of individuals with an inherited thrombophilia if the female family member is pregnant or considering pregnancy or oral contraceptive use OR ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
F5	**Factor V Leiden thrombophilia gene testing:** ☐ Diagnostic evaluation of individuals with a prior venous thromboembolism (VTE) during pregnancy or puerperium ☐ For patients with VTE with a personal or family history of recurrent VTE (more than two in the same person) ☐ For patients with their first VTE before age 50 with no precipitating factors ☐ For venous thrombosis at unusual sites such as the cerebral, mesenteric, portal, or hepatic veins ☐ For VTE associated with the use of estrogen-containing oral contraceptives, selective estrogen receptor modulators (SERMs), or hormone replacement therapy (HRT) ☐ To diagnose an inherited thrombophilia in female family members of individuals with an inherited thrombophilia if the female family member is pregnant or considering pregnancy or oral contraceptive use OR ☐ Other indication		
FBN1	☐ To facilitate the diagnosis of Marfan syndrome in patients who do not fulfill the Ghent diagnostic criteria, but have at least one major feature of the condition ☐ To facilitate the diagnosis of Marfan syndrome in the at-risk relatives of patients carrying known disease-causing variants ☐ Other indication		
FLCN	☐ To confirm a diagnosis of Birt-Hogg-Dubé Syndrome (BHD) in patients with suspected BHD ☐ Other indication		
FLT3	☐ For diagnosis and prognosis in acute myeloid leukemia (AML) ☐ Other indication		
FMR1	**FMR1 gene testing:** ☐ For CGG repeat length for diagnosis of patients of either sex with mental retardation, intellectual disability, developmental delay, or autism ☐ Other indication **FMR1 testing for fragile X-associated tremor/ataxia syndrome:** ☐ Males and females older than age 50 years who have progressive cerebellar ataxia and intention tremor with or without a positive family history of FMR1-related disorders in whom other common causes of ataxia have been excluded ☐ Women with unexplained premature ovarian insufficiency (POI) ☐ Other indication OR ☐ Other indication		
FoundationOne® Heme	☐ Assessment of gene alterations in hematologic malignancies ☐ Assessment of gene alterations in sarcomas ☐ Other indication		
GCK	☐ Diagnosis of maturity-onset diabetes of the young type 2 (MODY2) in patients with hyperglycemia or non-insulin–dependent diabetes who have a family history of abnormal glucose metabolism in at least two consecutive generations, with the patient or ≥ 1 family member(s) diagnosed before age 25 ☐ Other indication		
GJB2	☐ Diagnosis of DFNB1 or DFNA3 in individuals with nonsyndromic hearing loss to aid in treatment ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
GJB6	☐ Diagnosis of DFNB1 or DFNA3 in individuals with nonsyndromic hearing loss to aid in treatment ☐ Other indication		
HBA1/HBA2	☐ To confirm the diagnosis of alpha-thalassemia in a symptomatic individual ☐ To confirm the diagnosis in a pregnant woman with low hemoglobin when alpha-thalassemia is suspected ☐ Other indication		
HEXA	☐ As an adjunct to biochemical testing in patients with low hexosaminidase A levels in blood; When individuals are identified with apparent deficiency of hexosaminidase A enzymatic activity, targeted mutation analysis can then be used to distinguish pseudodeficiency alleles from disease-causing alleles ☐ Other indication		
HFE	☐ Diagnosis of patients with or without symptoms of iron overload with a serum transferrin saturation > 45% and/or elevated serum ferritin ☐ Other indication		
HLA	☐ To determine histocompatibility of tissue between organ and bone marrow donors and recipients prior to transplant ☐ For platelet transfusion for patients refractory to treatment due to alloimmunization ☐ Diagnosis of celiac disease in symptomatic patients with equivocal results on small bowel biopsy and serology, or in previously symptomatic patients who are asymptomatic while on a gluten-free diet ☐ Testing for the HLA-B*1502 allele prior to initiating treatment with carbamazepine in patients from high-risk ethnic groups ☐ Testing for the HLA-B*5701 allele for hypersensitivity reactions in patients prior to initiation or re-initiation with treatments containing abacavir ☐ Testing for the HLA-B*58:01 allele in patients prior to initiating treatment with allopurinol ☐ Other indication		
HNF1A	☐ Diagnosis of maturity-onset diabetes of the young type 3 (MODY3) in patients with hyperglycemia or non-insulin–dependent diabetes who have a family history of abnormal glucose metabolism in at least two consecutive generations, with the patient or ≥ 1 family member(s) diagnosed before age 25 ☐ Other indication		
HNF1B	☐ Diagnosis of maturity-onset diabetes of the young type 5 (MODY5) in patients with hyperglycemia or non-insulin–dependent diabetes who have a family history of abnormal glucose metabolism in at least two consecutive generations, with the patient or ≥ 1 family member(s) diagnosed before age 25, and who have structural or functional abnormalities of the kidneys ☐ Other indication		
HNF4A	☐ Diagnosis of maturity-onset diabetes of the young type 1 (MODY1) in patients with hyperglycemia or non-insulin–dependent diabetes who have a family history of abnormal glucose metabolism in at least two consecutive generations, with the patient or ≥ 1 family member(s) diagnosed before age 25 ☐ Other indication		
HTT	☐ To test for CAG repeat length for diagnosis of Huntington's/chorea disease (HD) in patients suspected of having HD in the absence of a family history of HD ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
IGH	☐ For medical management of patients with acute lymphoblastic leukemia (ALL) through analysis of rearrangements in the IGH gene to estimate minimal residual disease (MRD) levels ☐ For diagnostic evaluation of rearrangements in the IGH gene in patients with suspected B-cell non-Hodgkin lymphoma (NHL), but in whom clinical, immunophenotypic, and histologic evaluation have provided inconclusive results ☐ Other indication		
IGK	☐ For medical management of patients with acute lymphoblastic leukemia (ALL) through analysis of rearrangements in the IGK gene to estimate minimal residual disease (MRD) levels ☐ For diagnostic evaluation of rearrangements in the IGK gene in patients with suspected B-cell non-Hodgkin lymphoma (NHL), but in whom clinical, immunophenotypic and histologic evaluation have provided inconclusive results ☐ Other indication		
IL28B	☐ For IL28B single nucleotide polymorphism (SNP) testing in patients with chronic hepatitis C virus (HCV) genotype 1 being considered for treatment with PegIFN/RBV dual therapy ☐ Other indication		
JAK2	☐ Diagnostic evaluation of individuals presenting with clinical, laboratory, or pathological findings suggesting classic forms of myeloproliferative neoplasms (MPN), that is, polycythemia vera (PV), essential thrombocythemia (ET), or primary myelofibrosis (PMF) ☐ Diagnostic evaluation of PV through JAK2 exon 12 variant detection in JAK2 p.Val617Phe-negative individuals ☐ Other indication		
KCNQ1, KCNH2, SCN5A, KCNE1, and/or KCNE2	☐ For patients with suspected familial long QT syndrome for confirmation of diagnosis and treatment ☐ Other indication		
KIT	☐ To confirm a diagnosis of a gastrointestinal stromal tumor (GIST) in patients who are negative by immunostaining ☐ To determine primary resistance to treatment with tyrosine kinase inhibitors (TKI) in patients with an advanced metastatic or unresectable GIST ☐ To determine primary resistance to preoperative or postoperative treatment of a GIST with TKIs ☐ Other indication		
KMT2D and/or KDM6A	☐ Diagnosis of Kabuki syndrome (KS) in patients with symptoms compatible with KS ☐ Other indication		
KRAS	☐ To help guide administration of anti-epidermal growth factor receptor (EGFR) monoclonal antibodies ☐ Other indication		
MDxHealth Confirm MDx	☐ Men with a previous diagnosis of prostate cancer that have undergone a previous prostate biopsy (within prior 24 months) and are being considered for a repeat prostate biopsy due to persistent cancer-risk factors ☐ Men with a previous diagnosis of prostate cancer that have undergone a previous prostate biopsy (within prior 24 months) and are being considered for a repeat prostate biopsy due to elevated cancer risk factors ☐ Other indication		
MDxHealth Select MDx	☐ Men with previous diagnosis of prostate cancer that are suspected of harboring prostate cancer ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
MECP2	☐ Testing for MECP2 sequence variants in patients who meet established clinical diagnostic criteria for classic or variant Rett syndrome (RS) ☐ Testing for MECP2 sequence variants in patients who have symptoms of RS, but do not meet established clinical diagnostic criteria ☐ Other indication		
MEFV	☐ In patients exhibiting symptoms of familial Mediterranean fever (FMF), including periodic episodes of fever in combination with peritonitis, pleuritic, arthritis, and erysipelas-like erythema ☐ In patients from ethnic groups considered at high risk for FMF who present with nephrotic syndrome or amyloidosis, but do not meet the diagnostic criteria for FMF ☐ Other indication		
MLH1, MSH2, MSH6, MSI, PMS2, and/or EPCAM	☐ Genetic testing for Lynch syndrome (LS) must be in accordance with the most current National Comprehensive Cancer Network (NCCN) guidelines for colon cancer ☐ Other indication		
MPL	☐ Diagnostic evaluation of myeloproliferative leukemia (MPL) variants to include Trp515Leu and Trp515Lys in JAK2 p.Val617Phe-negative individuals showing symptoms ☐ Other indication		
MUTYH	☐ Diagnosis of MUTYH (MYH)-associated polyposis (MAP) in APC-negative colorectal polyposis patients, or in polyposis patients who have a family history consistent with autosomal recessive inheritance ☐ Diagnosis of MAP in asymptomatic siblings of patients with known MYH variants ☐ Other indication		
Noninvasive Prenatal Screening for Trisomies 13, 18, 21, X & Y	☐ In singleton pregnancies with a high risk of fetal aneuploidy (for dates March 5, 2015-August 16, 2020). Specify date: ☐ In accordance with the most current ACOG guidelines ☐ Other indication **Note:** Pre-authorization is not required.		
NPM1	☐ To guide treatment decisions for individuals with acute myeloid leukemia (AML) ☐ Other indication		
NRAS	☐ For patients with metastatic colorectal cancer who are being considered for treatment with anti-epidermal growth factor receptor (EGFR) monoclonal antibodies, and who have had negative KRAS gene testing ☐ Other indication		
Oncotype DX® Breast Cancer Assay (Oncotype DX®)	☐ Estrogen receptor (ER) positive (+), lymph node (LN) negative (-), human epidermal growth factor receptor (EGFR) 2 negative (HER2-) breast cancer patients who are considering whether to use adjuvant chemotherapy in addition to standard hormone therapy ☐ ER+, HER2- breast cancer patients with 1-3 involved ipsilateral axillary lymph nodes who are considering whether to use adjuvant chemotherapy in addition to hormonal therapy ☐ Other indication		
PAX8	☐ For individuals with indeterminate thyroid fine-needle aspiration (FNA) biopsy cytology for diagnosis of papillary thyroid carcinoma ☐ Other indication		
PDGFRA	☐ To confirm a diagnosis of a gastrointestinal stromal tumor (GIST) in patients who are negative by immunostaining ☐ To determine primary resistance to treatment with tyrosine kinase inhibitors (TKI) in patients with an advanced metastatic or unresectable GIST ☐ To determine primary resistance to preoperative or postoperative treatment of a GIST with TKIs ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
PML/RARalpha	☐ Diagnostic assessment of individuals with suspected acute promyelocytic leukemia (APL) by quantitative RT-PCR (RQ-PCR) ☐ Diagnostic assessment of individuals with suspected APL by qualitative RT-PCR ☐ Monitoring response to treatment and disease progression in individuals with APL by RQ-PCR ☐ Other indication		
PMP22	☐ For the accurate diagnosis and classification of hereditary polyneuropathies ☐ Other indication		
PPP2R2B	☐ Diagnosis of spinocerebellar ataxia type 12 (SCA12) in patients with action tremor of the upper extremities and signs of cerebellar and cortical dysfunction, in addition to Indian ancestry and a family history consistent with autosomal dominant inheritance ☐ Diagnosis of SCA12 in symptomatic family members of known SCA12 patients ☐ Other indication		
PRSS1	**To confirm diagnosis of hereditary pancreatitis in symptomatic patients with any of the following:** ☐ A family history of pancreatitis in a first-degree (parent, sibling, child) or second-degree (aunt, uncle, grandparent) relative; ☐ An unexplained episode of documented pancreatitis occurring in a child that has required hospitalization, and where there is significant concern that hereditary pancreatitis should be excluded; ☐ Recurrent (two or more separate, documented episodes with hyperamylasemia) attacks of acute pancreatitis for which there is no explanation (anatomical anomalies, ampullary or main pancreatic strictures, trauma, viral infection, gallstones, alcohol, drugs, hyperlipidemia, etc.); or ☐ Unexplained (idiopathic) chronic pancreatitis OR ☐ Other indication		
PTEN	☐ For patients with autism spectrum disorders (ASD) and macrocephaly (head circumference greater than 2 standard above the mean for age) ☐ PTEN variant testing in individuals suspected of being affected with Cowden syndrome (CS) or Bannayan-Riley-Ruvalcaba syndrome (BRRS) ☐ Other indication		
RET	☐ Multiple endocrine neoplasia type 2 (MEN2) gene testing in patients with the clinical manifestations of MEN2A, MEN2B, or familial medullary thyroid carcinoma (FMTC), including those with apparently sporadic medullary thyroid carcinoma (MTC) or pheochromocytoma ☐ MEN2 gene testing to confirm a diagnosis in the at-risk relatives of genetically confirmed MEN2 patients ☐ Other indication		
ROS1	☐ For patients who have wild type (negative) epidermal growth factor receptor (EGFR) or ALK gene testing, reflex testing to ROS1 should be ordered for the treatment of non-small cell lung carcinoma ☐ Other indication		
RYR1	☐ To test clinically confirmed malignant hyperthermia susceptibility (MHS) patients for variants in the RYR1 gene to facilitate diagnostic testing in at-risk relatives ☐ To diagnose MHS in at-risk relatives of patients with clinically confirmed MHS ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
SDHA, SDHB, SDHC, SDHD, SDHAF2, MAX, and/or TMEM127	☐ To diagnose a hereditary paraganglioma (PGL) or pheochromocytoma (PCC) syndrome in patients with PGLs and/or PCCs ☐ Other indication		
SERPINA1	☐ For guidance in diagnosis of inconclusive cases of alpha-1 antitrypsin (AAT) deficiency (AATD) in individuals with chronic obstructive pulmonary disease (COPD), unexplained liver disease, family history of AATD, or environmental exposures leading to airflow obstruction after serum AAT protein levels and protein phenotyping has been completed ☐ Other indication		
SMAD4	☐ To clarify the diagnosis of individuals with juvenile polyposis syndrome (JPS) ☐ If a known SMAD4 mutation is in the family, genetic testing should be performed in the first six months of life due to hereditary hemorrhagic telangiectasia risk ☐ Other indication		
SMN1/SMN2	☐ Diagnosis of patients with hypotonia and muscle weakness who are suspected of having spinal muscular atrophy (SMA) ☐ Other indication		
SNRPN/UBE3A	**When a clinical diagnosis of Prader-Willi syndrome is suspected, the following findings justify genetic testing:** ☐ From birth to age two: hypotonia with poor suck (neonatal period) ☐ From age two to age six: hypotonia with history of poor suck, global developmental delay ☐ From age six to age 12: hypotonia with history of poor suck, global developmental delay, excessive eating with central obesity if uncontrolled ☐ From age 13 years to adulthood: cognitive impairment, usually mild intellectual disability; excessive eating with central obesity if uncontrolled, hypothalamic hypogonadism and/or typical behavior problems ☐ Other indication **When a clinical diagnosis of Angelman syndrome is suspected, the following findings justify genetic testing:** ☐ As part of the evaluation of patients with developmental delay, regardless of age ☐ As part of the evaluation of patients with a balance or movement disorder such as ataxia of gait; may not appear as frank ataxia but can be forward lurching, unsteadiness, clumsiness, or quick, jerky motions ☐ As part of the evaluation of patients with uniqueness of behavior: any combination of frequent laughter/smiling; apparent happy demeanor; easily excitable personality, often with uplifted hand-flapping or waving movements; hypermotoric behavior ☐ Speech impairment, none or minimal use of words; receptive and non-verbal communication skills higher than verbal ones ☐ Other indication OR ☐ Other indication		
STK11	☐ To confirm a diagnosis of Peutz-Jeghers syndrome (PJS) in proband patients with a presumptive or probable diagnosis of PJS ☐ Other indication		
TBP	☐ Diagnosis of spinocerebellar ataxia type 17 (SCA17) in ataxia patients exhibiting variable combinations of cognitive decline, psychiatric disturbance, and movement disorders ☐ Diagnosis of SCA17 in symptomatic family members of known SCA17 patients ☐ Diagnosis of SCA17 in patients suspected of having Huntington's disease (HD) who have tested negative for a pathogenic variant in the HD gene ☐ Other indication		

COLUMN I Select the gene(s) being requested	COLUMN II Select the indication(s) for the requested test	COLUMN III Indicate the CPT® code(s) and quantity	
		CPT® code(s)	QTY
TGFBR2	☐ To facilitate the diagnosis of Marfan syndrome in patients testing negative for FBN1 gene variants ☐ Other indication		
TP53	☐ Diagnosis of patients satisfying the criteria for classic Li-Fraumeni syndrome or Li-Fraumeni-like syndrome, or the Chompret criteria for TP53 gene testing ☐ Other indication		
TPMT	☐ TPMT genotyping or phenotyping in patients with inflammatory bowel disease (IBD) prior to administration of thiopurines (azathioprine, 6-MP, and 6-TG) ☐ Other indication		
TRG	☐ Diagnosis and treatment of T-cell neoplasms ☐ Other indication		
UGT1A1	☐ Prior to irinotecan administration in patients with colorectal cancer (CRC) to lower the starting does of irinotecan in patients with the UGT1A1*28/UGT1A1*28 genotype ☐ Prior to irinotecan administration in patients with CRC to increase the starting does of irinotecan in patients with the UGT1A1*1/ UGT1A1*1 or UGT1A1*1/UGT1A1*28 genotypes ☐ Other indication		
UPD	☐ For neonates, infants, children or adults symptomatic for Beckwith-Wiedermann syndrome (BWS) to diagnose uniparental disomy (UPD) for chromosome 11 ☐ Other indication		
VHL	☐ Diagnosis of Von Hippel-Lindau (VHL) syndrome in patients presenting with pheochromocytoma, paraganglioma or central nervous system hemangioblastoma ☐ Confirmation of diagnosis in individuals with symptoms consistent with VHL syndrome ☐ Other indication		
VKORC1	☐ For the initiation and management of warfarin treatment ☐ Other indication		
Y Chromosome Microdeletion Analysis	☐ For detecting submicroscopic deletions involving the Y chromosome in men with azoospermia, oligozoospermia or teratozoospermia ☐ Other indication		

SECTION II – LDTs that are NOT covered under the DHA Evaluation of Non-U.S. FDA Approved LDT Demonstration Project (test/gene not listed in Section I)

Please list the exact genetic test name, CPT® code(s), FDA approval status of the test, and the name of the laboratory performing the test.

Single gene name:
CPT codes:
Is this an FDA-approved test? Visit www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm to verify. ☐ **Yes** ☐ **No** ☒ **Unknown**
Which laboratory is performing the genetic test?

SECTION III – Panel tests. To be considered for coverage under DHA Evaluation of Non-U.S. FDA Approved LDT Demonstration Project, panel tests must include at least one gene listed in Section 1.

Panel test name:
CPT codes:
Does the requested panel test include any genes listed in Section I? ☐ **Yes** **If yes, go back to Section I and mark all the gene(s) in Column I that are within the panel test AND select the indication for those gene(s) in Column II. (You do not need to complete Column III)** ☐ **No**
Is this an FDA-approved test? Visit www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm to verify. ☐ **Yes** ☐ **No** ☐ **Unknown**
Which laboratory is performing the genetic test?

I attest the information provided is true and accurate to the best of my knowledge. I understand Health Net Federal Services, LLC or designee may perform a routine audit and request the medical documentation to verify the accuracy of the information reported on this form.

Additional information: _____

Physician's printed name and title: _____

Tax Identification Number (TIN): _____

Physician signature: _____ Date: _____

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