APPROVED LABORATORY DEVELOPED TESTS (LDTs): BY TEST NAME OR BY GENE(S) TESTED	
New additions are in red font	
TEST NAME:	**Afirma Thyroid FNA Analysis**
Effective Date:	19-Oct-17
Coverage Guidelines:	The Afirma Thyroid FNA Analysis is covered for the following indication: • To aid in thyroid nodule diagnosis by reducing unnecessary surgeries in patients with indeterminate thyroid nodules.
GENE:	**ALK**
Effective Date:	1-Jan-13
Coverage Guidelines:	ALK gene testing is covered for the following indication: • 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.
GENE:	**APC**
Effective Date:	1-Jan-13
Coverage Guidelines:	APC gene testing is covered for the following indications: • 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.
GENE:	**ATXN1**
Effective Date:	1-Jan-13
Coverage Guidelines:	ATXN1 gene testing is covered for the following indications: • 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.
GENE:	**ATXN2**
Effective Date:	1-Jan-13
Coverage Guidelines:	ATXN2 gene testing is covered for the following indications: • 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.
GENE:	**ATXN3**
Effective Date:	1-Jan-13
Coverage Guidelines:	ATXN3 gene testing is covered for the following indications: • 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.
GENE:	**ATXN7**
Effective Date:	1-Jan-13
Coverage Guidelines:	ATXN7 gene testing is covered for the following indications: • 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.

GENE:	**ATXN10**
Effective Date:	1-Jan-13
Coverage Guidelines:	ATXN10 gene testing is covered for the following indications: • 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.
GENE:	**BCR/ABL1**
Effective Date:	1-Jan-13
Coverage Guidelines:	BCR/ABL1 gene testing is covered for the following indications: • 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 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.
TEST NAME:	**Biotheranostics Breast Cancer Index**
Effective Date:	1-Jan-23
Coverage Guidelines:	The Biotheranostics Breast Cancer Index is covered for the following indications: • 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.
GENE:	**BMPR1A**
Effective Date:	1-Jan-13
Coverage Guidelines:	BMPR1A gene testing is covered for the following indications: • 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.
GENE:	**BRAF**
Effective Date:	1-Jan-13
Coverage Guidelines:	BRAF gene testing is covered for the following indications: • 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.
GENE:	**BRCA1/BRCA2**
Effective Date:	1-Jan-13
Coverage Guidelines:	BRCA1/BRCA2 gene testing is covered in accordance with the most current National Comprehensive Cancer Network (NCCN) Guidelines for Breast Cancer.
GENE:	**CACNA1A**
Effective Date:	1-Jan-13
Coverage Guidelines:	CACNA1A gene testing is covered for the following indications: • 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.
GENE:	**CALM1, CASQ2, RYR2, and/or TRDN**
Effective Date:	1-Jan-13
Coverage Guidelines:	CALM1, CASQ2, RYR2, and/or TRDN gene testing is covered for the following indication: • To confirm a diagnosis of Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) in patients with clinically diagnosed or suspected CPVT.
GENE:	**CDH1**
Effective Date:	1-Jan-13

Coverage Guidelines:	CDH1 gene testing is covered for the following indication: • For large rearrangements in the CDH1 gene for the treatment of Hereditary Diffuse Gastric Cancer (HDGC).
GENE:	**CEBPA**
Effective Date:	1-Jan-13
Coverage Guidelines:	CEBPA gene testing is covered for the following indication: • To guide the treatment decisions for individuals with Acute Myeloid Leukemia (AML).
GENE:	**CFTR**
Effective Date:	1-Jan-13
Coverage Guidelines:	CFTR gene testing is covered for the following indications: • 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. • Preconception and prenatal carrier screening in accordance with the most current ACOG guidelines.
	Note: Effective December 27, 2021, CFTR gene testing as a preconception and prenatal carrier screening is no longer covered under this demonstration and is covered as a TRICARE Basic benefit. See TPM, Chapter 6, Section 3.2. All other coverage guidelines for CFTR gene testing noted above remain under the LDT demonstration.
GENE:	**Chimerism Analysis**
Effective Date:	1-Jan-13
Coverage Guidelines:	Chimerism analysis is covered for the following indication: • For the management and treatment of stem cell transplant patients.
GENE:	**Chromosome 22q11.2**
Effective Date:	1-Jan-13
Coverage Guidelines:	Chromosome 22q11.2 gene testing is covered for the following indication: • Confirmation of diagnosis in an individual suspected of chromosome 22q11.2 deletion syndrome based on clinical findings.
GENE:	**COL1A1/COL1A2**
Effective Date:	1-Jan-13
Coverage Guidelines:	COL1A1/COL1A2 gene testing is covered for the following indication: • 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.
GENE:	**COL3A1**
Effective Date:	1-Jan-13

Coverage Guidelines:	COL3A1 gene testing is covered for the following indication: • 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.
GENE:	**CYP2C9**
Effective Date:	1-Jan-13
Coverage Guidelines:	CYP2C9 gene testing is covered for the following indication: • For the initiation and management of warfarin treatment.
GENE:	**CYP2C19**
Effective Date:	1-Jan-13
Coverage Guidelines:	CYP2C19 gene testing is covered for the following indication: • To manage dosing of clopidogrel.
GENE:	**Cytogenomic Constitutional Microarray Analysis**
Effective Date:	1-Jan-13
Coverage Guidelines:	Cytogenomic Constitutional Microarray Analysis gene testing is covered for the following indications: • Diagnostic evaluation of patients suspected of having a genetic syndrome (i.e., have congenital anomalies, dysmorphic features, Developmental Delay (DD), and/or intellectual disability). • Diagnostic evaluation of individuals with Autism Spectrum Disorder (ASD), including autism, Asperger syndrome, and pervasive developmental disorder.
GENE:	**DAZ/SRY**
Effective Date:	1-Jan-13
Coverage Guidelines:	DAZ/SRY gene testing is covered for the following indication: • To detect submicroscopic deletions involving the Y chromosome in the evaluation of men with infertility secondary to azoospermia, oligozoospermia, or teratozoospermia.
TEST NAME:	**DermTech Pigmented Lesion Assay (PLSA)**
Effective Date:	1-Jan-23
Coverage Guidelines:	The DermTech Pigmented Lesion Assay is covered for the following indication: • Neoplasms of uncertain behavior of skin.
GENE:	**DMD**
Effective Date:	20-Nov-14
Coverage Guidelines:	DMD gene testing is covered for the following indication: • For diagnostic DMD testing (deletion and duplication analysis with reflex to complete gene sequencing) in males or females exhibiting symptoms of Duchenne Muscular Dystrophy (DMD) or Becker Muscular Dystrophy (BMD).
GENE:	**DMPK**
Effective Date:	1-Jan-13
Coverage Guidelines:	DMPK gene testing is covered for the following indications: • 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.
GENE:	**DSC2, DSG2, DSP, JUP, PKP2, RYR2, TGFB3, and/or TMEM43**
Effective Date:	1-Jan-13

Coverage Guidelines:	DSC2, DSG2, DSP, JUP, PKP2, RYR2, TGFB3, and/or TMEM43 gene testing is covered for the following indications: • 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.
GENE:	**DYT1/TOR1A**
Effective Date:	1-Jan-13
Coverage Guidelines:	DYT1/TOR1A gene testing is covered for the following indications: • 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.
GENE:	**Avise Lupus (Exagen)**
Effective Date:	**1-Mar-24**
Coverage Guidelines:	• Patients with laboratory evidence of autoimmune condition and suspected systemic lupus erythematous (SLE)
GENE:	**EGFR**
Effective Date:	1-Jan-13
Coverage Guidelines:	EGFR gene testing is covered for the following indication: • To help guide administration of Epidermal Growth Factor Receptor (EGFR) TKIs in the first-line treatment of non-small cell lung cancer.
GENE:	**F2**
Effective Date:	1-Jan-13
Coverage Guidelines:	Prothrombin (Factor II) related thrombophilia gene testing is covered for the following indications: • 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.
GENE:	**F5**
Effective Date:	1-Jan-13
Coverage Guidelines:	Factor V Leiden thrombophilia gene testing is covered for the following indications: • Diagnostic evaluation of individuals with a prior 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.

GENE:	**FBN1**
Effective Date:	1-Jan-13
Coverage Guidelines:	FBN1 gene testing is covered for the following indications: • 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.
GENE:	**FLCN**
Effective Date:	31-Jul-14
Coverage Guidelines:	FLCN gene testing is covered for the following indication: • To confirm a diagnosis of Birt-Hogg-Dubé Syndrome (BHD) in patients with suspected BHD.
GENE:	**FLT3**
Effective Date:	7-Oct-13
Coverage Guidelines:	FLT3 gene testing is covered for the following indication: • For diagnosis and prognosis in AML.
GENE:	**FMR1**
Effective Date:	1-Jan-13
Coverage Guidelines:	FMR1 gene testing is covered for the following indications: • Testing for CGG repeat length for diagnosis of patients of either sex with mental retardation, intellectual disability, developmental delay, or autism. FMR1 gene testing for Fragile X-Associated Tremor/Ataxia Syndrome is covered for the following individuals: • 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).
TEST NAME:	**FoundationOne® Heme**
Effective Date:	1-Jan-23
Coverage Guidelines:	The FoundationOne® Heme assay is covered for the following indications: • Assessment of gene alterations in hematologic malignancies. • Assessment of gene alterations in sarcomas.
GENE:	**GCK**
Effective Date:	1-Jan-13
Coverage Guidelines:	GCK gene testing is covered for the following indication: • 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.
GENE:	**GJB2**
Effective Date:	1-Jan-13
Coverage Guidelines:	GJB2 gene testing is covered for the following indication: • Diagnosis of DFNB1 or DFNA3 in individuals with nonsyndromic hearing loss to aid in treatment.
GENE:	**GJB6**
Effective Date:	1-Jan-13
Coverage Guidelines:	GJB6 gene testing is covered for the following indication: • Diagnosis of DFNB1 or DFNA3 in individuals with nonsyndromic hearing loss to aid in treatment.
TEST NAME:	**GRAIL Galleri**
Effective Date:	23-Oct-23
Coverage Guidelines:	• Adults, age 50 or older, with elevated risk for cancer
TEST NAME:	**Guardant360: TissueNext, Reveal**
Effective Date:	1-Feb-24
Coverage Guidelines:	• Patients with diagnosed cancers, to guide treatment decisions and/or in the consideration of targeted therapies
TEST NAME:	**Guardant360: Response**
Effective Date:	1-Feb-24
Coverage Guidelines:	• Patients with advanced solid tumor-originating cancers that were previously tested with Guardant 360 or Guardant 360 CDx

GENE:	HBA1/HBA2
Effective Date:	1-Jan-13
Coverage Guidelines:	HBA1/HBA2 gene testing is covered for the following indications: • 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.
GENE:	**HEXA**
Effective Date:	1-Jan-13
Coverage Guidelines:	HEXA gene testing is covered for the following indication: • 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.
GENE:	**HFE**
Effective Date:	1-Jan-13
Coverage Guidelines:	HFE-associated hereditary hemochromatosis gene testing is covered for the following indication: • Diagnosis of patients with or without symptoms of iron overload with a serum transferrin saturation >45% and/or elevated serum ferritin.
GENE:	**HLA**
Effective Date:	1-Jan-13
Coverage Guidelines:	HLA gene testing is covered for the following indications: • 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 reinitiation with treatments containing abacavir. • Testing for the HLA-B*58:01 allele in patients prior to initiating treatment with allopurinol.
GENE:	**HNF1A**
Effective Date:	1-Jan-13
Coverage Guidelines:	HNF1A gene testing is covered for the following indication: • 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.
GENE:	**HNF1B**
Effective Date:	1-May-16
Coverage Guidelines:	HNF1B gene testing is covered for the following indication: • 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.

GENE:	HNF4A
Effective Date:	1-May-16
Coverage Guidelines:	HNF4A gene testing is covered for the following indication: • 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.
GENE:	**HTT**
Effective Date:	1-Jan-13
Coverage Guidelines:	HTT gene testing is covered for the following indication: • To test for CAG repeat length for diagnosis of Huntington Chorea/Disease (HD) in patients suspected of having HD in the absence of a family history of HD.
GENE:	**IGH**
Effective Date:	1-Jan-13
Coverage Guidelines:	IGH gene testing is covered for the following indications: • 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's Lymphoma (NHL), but in whom clinical, immunophenotypic, and histologic evaluation have provided inconclusive results.
GENE:	**IGK**
Effective Date:	1-Jan-13
Coverage Guidelines:	IGK gene testing is covered for the following indications: • For medical management of patients with ALL through analysis of rearrangements in the IGK gene to estimate MRD levels. • For diagnostic evaluation of rearrangements in the IGK gene in patients with suspected B-cell NHL, but in whom clinical, immunophenotypic, and histologic evaluations have provided inconclusive results.
GENE:	**IL28B**
Effective Date:	28-Feb-13
Coverage Guidelines:	IL28B gene testing is covered for the following indication: • 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.
GENE:	**JAK2**
Effective Date:	1-Jan-13
Coverage Guidelines:	JAK2 gene testing is covered for the following indications: • 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.
GENE:	**KCNQ1, KCNH2, SCN5A, KCNE1, and/or KCNE2**
Effective Date:	1-Jan-13
Coverage Guidelines:	KCNQ1, KCNH2, SCN5A, KCNE1, and/or KCNE2 gene testing is covered for the following indication: • For patients with suspected familial Long QT Syndrome for confirmation of diagnosis and treatment.

GENE:	**KIT**
Effective Date:	1-Jan-13
Coverage Guidelines:	KIT gene testing is covered for the following indications: • To confirm a diagnosis of a gastrointestinal stromal tumor (GIST) in patients who are negative by immunostaining • To determine primary resistance to treatment with TKIs in patients with an advanced metastatic or unresectable GIST. • To determine primary resistance to preoperative or postoperative treatment of a GIST with TKIs.
GENE:	**KMT2D and/or KDM6A**
Effective Date:	1-Jan-13
Coverage Guidelines:	KMT2D and/or KDM6A gene testing is covered for the following indication: • To confirm a diagnosis of Kabuki Syndrome (KS) in patients with symptoms compatible with KS.
GENE:	**KRAS**
Effective Date:	1-Jan-13
Coverage Guidelines:	KRAS gene testing is covered for the following indication: • To help guide administration of anti-EGFR monoclonal antibodies.
TEST NAME:	**Labcorp PlasmaFocus**
Effective Date:	23-Oct-23
Coverage Guidelines:	• Patients diagnosed with solid cancers
TEST NAME:	**MDxHealth Confirm MDx**
Effective Date:	1-Jan-23
Coverage Guidelines:	The MDxHealth Confirm MDx is covered for the following indications: • 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.
TEST NAME:	**MDxHealth Select MDx**
Effective Date:	1-Jan-23
Coverage Guidelines:	The MDxHealth Select MDx is covered for the following indications: • Men with previous diagnosis of prostate cancer that are suspected of harboring prostate cancer.
GENE:	**MECP2**
Effective Date:	1-Jan-13
Coverage Guidelines:	MECP2 gene testing is covered for the following indications: • 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.
GENE:	**MEFV**
Effective Date:	16-Jun-14
Coverage Guidelines:	MEFV gene testing is covered for the following indications: • 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.
GENE:	**MLH1, MSH2, MSH6, MSI, PMS2, and/or EPCAM**
Effective Date:	1-Jan-13
Coverage Guidelines:	Genetic testing for Lynch Syndrome (LS) is covered in accordance with the most current NCCN Guidelines for Colon Cancer.
GENE:	**MPL**
Effective Date:	1-Jan-13
Coverage Guidelines:	MPL gene testing is covered for the following indication: • Diagnostic evaluation of Myeloproliferative Leukemia (MPL) variants to include Trp515Leu and Trp515Lys in JAK2 p.Val617Phe-negative individuals showing symptoms.
GENE:	**MUTYH**
Effective Date:	1-Jan-13
Coverage Guidelines:	MUTYH or MYH gene testing is covered for the following indications: • Diagnosis of 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.
GENE:	**Noninvasive Prenatal Screening for Trisomies 13, 18, 21, X & Y**
Effective Date:	17-Aug-20

Coverage Guidelines:	Nonivasive Prenatal Screening for Trisomies 13, 18, 21, X & Y is covered for the following indication: • In singleton pregnancies with a high risk of fetal aneuploidy. (For dates March 5, 2015 - August 16, 2020.) • In accordance with the most current ACOG guidelines.
	Note: Preauthorization is not required.
GENE:	**NPM1**
Effective Date:	1-Jan-13
Coverage Guidelines:	NPM1 gene testing is covered for the following indication: • To guide treatment decisions for individuals with AML.
GENE:	**NRAS**
Effective Date:	3-Oct-14
Coverage Guidelines:	NRAS gene testing is covered for the following indication: • For patients with metastatic colorectal cancer who are being considered for treatment with anti-EGFR monoclonal antibodies, and who have had negative KRAS gene testing.
TEST NAME:	**Oncotype DX® Breast Cancer Assay (Oncotype DX®)**
Effective Date:	1-Jan-13
Coverage Guidelines:	Oncotype DX® gene testing is covered for the following indications: • Estrogen Receptor (ER) positive (+), lymph node (LN) negative (-), human 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.
GENE:	**PAX8**
Effective Date:	1-Jan-13
Coverage Guidelines:	PAX8 gene testing is covered for the following indication: • For individuals with indeterminate thyroid FNA biopsy cytology for diagnosis of papillary thyroid carcinoma.
GENE:	**PDGFRA**
Effective Date:	1-Jan-13
Coverage Guidelines:	PDGFRA gene testing is covered for the following indications: • To confirm a diagnosis of a GIST in patients who are negative by immunostaining. • To determine primary resistance to treatment with TKIs in patients with an advanced metastatic or unresectable GIST. • To determine primary resistance to preoperative or postoperative treatment of a GIST with TKIs.

GENE:	PML/RARalpha
Effective Date:	1-Jan-13
Coverage Guidelines:	PML/RARalpha gene testing is covered for the following indications: • 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.
GENE:	**PMP22**
Effective Date:	1-Jan-13
Coverage Guidelines:	PMP22 gene testing is covered for the following indication: • For the accurate diagnosis and classification of hereditary polyneuropathies.
GENE:	**PPP2R2B**
Effective Date:	1-Jan-13
Coverage Guidelines:	PPP2R2B gene testing is covered for the following indications: • 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.
GENE:	**PRSS1**
Effective Date:	1-Jan-13
Coverage Guidelines:	PRSS1 gene testing is covered for the following indications: • To confirm a 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 hyper-amylasemia) 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.
GENE:	**PTEN**
Effective Date:	1-Jan-13
Coverage Guidelines:	PTEN gene testing is covered for the following indications: • For patients with ASDs 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).
GENE:	**RET**
Effective Date:	1-Jan-13
Coverage Guidelines:	RET gene testing is covered for the following indications: • 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.
GENE:	**ROS1**
Effective Date:	12-Jan-16
Coverage Guidelines:	ROS1 gene testing is covered for the following indication:. • For patients who have wild type (negative) EGFR or ALK gene testing, reflex testing to ROS1 should be ordered for the treatment of non-small cell lung carcinoma.
GENE:	**RYR1**
Effective Date:	1-Jan-13
Coverage Guidelines:	RYR1 gene testing is covered for the following indications: • 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.
GENE:	**SDHA, SDHB, SDHC, SDHD, SDHAF2, MAX, and/or TMEM127**
Effective Date:	16-Jun-14

Coverage Guidelines:	SDHA, SDHB, SDHC, SDHD, SDHAF2, MAX, and/or TMEM127 gene testing is covered for the following indication: • To diagnose a hereditary paraganglioma (PGL) or pheochromocytoma (PCC) syndrome in patients with PGLs and/or PCCs.
GENE:	**SERPINA1**
Effective Date:	27-May-14
Coverage Guidelines:	SERPINA1 gene testing is covered for the following indication: • For guidance in diagnosis of inconclusive cases of Alpha-1 Antitrypsin 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 Alpha-1 Antitrypsin (AAT) protein levels and protein phenotyping has been completed.
GENE:	**SMAD4**
Effective Date:	1-Jan-13
Coverage Guidelines:	SMAD4 gene testing is covered for the following indications: • To clarify the diagnosis of individuals with 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.
GENE:	**SMN1/SMN2**
Effective Date:	1-Jan-13
Coverage Guidelines:	SMN1/SMN2 gene testing is covered for the following indication: • Diagnosis of patients with hypotonia and muscle weakness who are suspected of having Spinal Muscular Atrophy (SMA).

GENE:	**SNRPN/UBE3A**
Effective Date:	1-Jan-13
Coverage Guidelines:	SNRPN/UBE3A gene testing is covered for the following indications: • When a clinical diagnosis of Prader-Willi Syndrome (PWS) 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. • 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.
GENE:	**STK11**
Effective Date:	1-Jan-13
Coverage Guidelines:	STK11 gene testing is covered for the following indication: • To confirm a diagnosis of Peutz-Jeghers Syndrome (PJS) in proband patients with a presumptive or probable diagnosis of PJS.
GENE:	**TBP**
Effective Date:	1-Jan-13
Coverage Guidelines:	TBP gene testing is covered for the following indications: • 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 Disease (HD) who have tested negative for a pathogenic variant in the HD gene.
GENE:	**TGFBR2**
Effective Date:	1-Jan-13
Coverage Guidelines:	TGFBR2 gene testing is covered for the following indication: • To facilitate the diagnosis of Marfan syndrome in patients testing negative for FBN1 gene variants.
GENE:	**TP53**
Effective Date:	1-Jan-13
Coverage Guidelines:	TP53 gene testing is covered for the following indication: • Diagnosis of patients satisfying the criteria for classic Li-Fraumeni Syndrome (LFS) or Li-Fraumeni-Like Syndrome (LFLS), or the Chompret criteria for TP53 gene testing.
GENE:	**TPMT**
Effective Date:	1-Jan-13
Coverage Guidelines:	TPMT gene testing is covered for the following indication: • TPMT genotyping or phenotyping in patients with Inflammatory Bowel Disease (IBD) prior to administration of thiopurines (azathioprine, 6-MP, and 6-TG).

GENE:	**TRG**
Effective Date:	1-Jan-13
Coverage Guidelines:	TRG gene testing is covered for the following indication: • Diagnosis and treatment of T-cell neoplasms.
GENE:	**UGT1A1**
Effective Date:	1-Jan-13
Coverage Guidelines:	UGT1A1 gene testing is covered for the following indications: • Prior to irinotecan administration in patients with CRC to lower the starting dose of irinotecan in patients with the UGT1A1*28/UGT1A1*28 genotype. • Prior to irinotecan administration in patients with CRC to increase the starting dose of irinotecan in patients with the UGT1A1*1/UGT1A1*1 or UGT1A1*1/UGT1A1*28 genotypes.
GENE:	**UPD**
Effective Date:	1-Jan-13
Coverage Guidelines:	UPD gene testing is covered for the following indication: • For neonates, infants, children or adults symptomatic for Beckwith-Wiedermann Syndrome (BWS) to diagnose Uniparental Disomy (UPD) for chromosome 11.
GENE:	**VHL**
Effective Date:	1-Jan-13
Coverage Guidelines:	VHL gene testing is covered for the following indications: • 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.
GENE:	**VKORC1**
Effective Date:	1-Jan-13
Coverage Guidelines:	VKORC1 gene testing is covered for the following indication: • For the initiation and management of warfarin treatment.
TEST NAME:	**Y Chromosome Microdeletion Analysis**
Effective Date:	1-Jan-13
Coverage Guidelines:	Y Chromosome Microdeletion Analysis is covered for the following indication: • For detecting submicroscopic deletions involving the Y chromosome in men with azoospermia, oligozoospermia, or teratozoospermia.

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