MASSACHUSETTS

MEDICAL POLICY ANNOUNCEMENTS

Posted July 2024

This document announces new medical policy changes that take effect October 1, 2024. Changes affect these specialties:

Cardiology
Cardiology Pulmonology Endocrinology
Multispecialty Non-invasive Vascular Studies
Obstetrics - Assisted Reproductive Services
Pulmonology

Carelon Genetic Testing Guidelines
Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer
Prenatal Screening] using cell free DNA
Somatic Testing of Solid Tumors
Somatic Testing of Hematologic Malignancies

Note that revised, clarified, or retired policies may have separate effective dates. See details in the table below.

CARDIOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Trans-esophageal Echo-cardiography (TEE)	114	**New medical policy** describing medically necessary and investigational indications. Local Coverage Determination Transesophageal Echocardiography L33579 is followed for Medicare Advantage products.	October 1, 2024	Commercial	No action required. Prior authorization is **not required.**
Transthoracic Echo-cardiography (TTE)	115	**New medical policy** describing medically necessary and not medically necessary indications. Local Coverage Determination Transthoracic Echocardiography L33577 is followed for	October 1, 2024	Commercial	No action required. Prior authorization is **not required.**

		Medicare Advantage products.			
Cardiac Catheterization and Coronary Angiography	116	**New medical policy** describing medically necessary and not medically necessary indications. Local Coverage Determination Cardiac Catheterization and Coronary Angiography L33557 is followed for Medicare Advantage products.	October 1, 2024	Commercial	No action required. Prior authorization is **not required.**
Percutaneous Coronary Intervention	117	**New medical policy** describing medically necessary indications and coverage limitations. Local Coverage Determination Percutaneous Coronary Intervention L33623 is followed for Medicare Advantage products.	October 1, 2024	Commercial	No action required. Prior authorization is **not required.**
Single Chamber and Dual Chamber Permanent Cardiac Pacemakers	118	**New medical policy** describing medically necessary and investigational indications. Billing and Coding: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers A54909 is followed for Medicare Advantage products.	October 1, 2024	Commercial	No action required. Prior authorization is **not required.**
Ambulatory Electro-cardiograph (AECG) Monitoring	119	**New medical policy** describing medically necessary and not medically necessary indications. Ambulatory Electrocardiograph (AECG) Monitoring L39490 is followed for Medicare Advantage products.	October 1, 2024	Commercial	No action required. Prior authorization is **not required.**

Leadless Cardiac Pacemakers	038	**Policy revised.** The Aveir™ DR dual chamber pacing system is considered investigational.	October 1, 2024	Commercial	No action required. Prior authorization is **not required.**
Implantable Cardioverter Defibrillator	070	**Policy revised.** Policy statements and policy guidelines updated for pediatric indications.	October 1, 2024	Commercial	No action required.

CARDIOLOGY PULMONOLOGY ENDOCRINOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Remote Patient Monitoring (RPM) and Remote Therapeutic Monitoring (RTM)	082	**Policy implementation delayed** until further notice. (This new policy was previously announced in June 2024 with an effective date of September 1, 2024.)	Delayed until further notice.	Commercial Medicare	No action required.
Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid and Artificial Pancreas Device Systems	107	**Policy revised.** Prior authorization is no longer required for type 2 diabetes for codes A4238, A4239 and A9277. Procedure-to-diagnoses edits will be implemented. **Policy clarified** to indicate that all other uses of CGM are considered investigational.	October 1, 2024	Commercial	No action required.

MULTISPECIALTY NON-INVASIVE VASCULAR STUDIES

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Non-invasive Vascular Studies	691	**Policy revised** to include medically necessary and	October 1, 2024	Commercial	No action required.

		investigational indications for cerebrovascular arterial studies (extracranial and transcranial doppler). Codes 93880, 93882, 93886, 93888, 93890, 93892, and 93893. Local Coverage Determination (LCD) Non-Invasive Vascular Studies L33627 is followed for Medicare Advantage products.			Prior authorization is still **not required.**

OBSTETRICS - ASSISTED REPRODUCTIVE SERVICES

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Assisted Reproductive Services	086	**Clarifications** made to the noncovered section for assisted embryo hatching.	July 1, 2024	Commercial	No action required.

PULMONOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Molecular Testing in the Management of Pulmonary Nodules	029	**Policy revised.** Investigational policy statements updated to include the REVEAL Lung Nodule characterization test.	October 1, 2024	Commercial	No action required.

GENETIC TESTING GUIDELINES

Legend	**Text color**	**Indicates…**
Guideline Change Summary	**Blue**	Change to guideline wording
	Black	Preservation of existing guideline wording
		Changes expected to be…
Explanation of Change	**Green**	More expansive on appropriateness
	Red	More restrictive on appropriateness
	Black	Have minimal if any impact on appropriateness review and exists primarily to clarify intent

The following updates will apply to the Carelon Clinical Appropriateness **Guidelines for Genetic Testing.** You may access and download a copy of the current guidelines here. For questions related to the guidelines, please contact Carelon via email at MedicalBenefitsManagement.guidelines@carelon.com

Carelon Guideline	Policy Change Summary	Effective Date
Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer		
Individuals with metastatic breast cancer who may benefit from PIK3CA/AKT1/PTEN or ESR1-targeted therapy	Liquid (ctDNA) based testing, to include PIK3CA, AKT1, PTEN and/or ESR1 somatic tumor testing, is considered medically necessary to identify individuals who may benefit from the use of alpelisib, capivasertib plus fulvestrant or elacestrant (or other FDA approved agents targeting these same pathways) when **ALL** of the following criteria are met: • The individual is either an adult man OR postmenopausal woman • The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for use per drug label of an applicable FDA approved targeted agent • The individual has not had prior testing for the targeted gene(s) of interest in the metastatic setting • There is insufficient tumor tissue available for NGS-based somatic profiling or tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition **Explanation of change** Expanded criteria to include a wider scope of testing for metastatic disease: AKT1 and PTEN (related to capivasertib/fulvestrant therapy) Clarifications	November 17, 2024
Individuals without malignancy for whom liquid biopsy is used for screening	**Not Medically Necessary:** **Individuals without malignancy for whom liquid biopsy is used for screening** • Liquid (ctDNA) based testing is considered not medically necessary for individuals without invasive malignancy for whom the liquid biopsy test is being used for early initial cancer diagnosis or cancer screening **Individuals with invasive solid tumor malignancy for whom liquid biopsy is used to assess for minimal residual disease (MRD) during and after treatment** • Liquid (ctDNA) based testing is considered not medically necessary for individuals with invasive solid tumor malignancy for whom the liquid biopsy test is being used to assess for MRD during and after treatment **Explanation of change** Clarified that liquid screening tests are not medically necessary	November 17, 2024

Carelon Guideline	Policy Change Summary	Effective Date
Prenatal Testing [change to Screening] using cell free DNA		

General Requirements	Prenatal screening using cfDNA should occur only once per fetus per pregnancy. **Explanation of change** Clarification – changed prenatal testing to prenatal screening throughout guideline	November 17, 2024
Condition-Specific Requirements	**Viable singleton or twin pregnancy** Prenatal screening using cell-free DNA (cfDNA) is considered **medically necessary** in viable singleton or twin pregnancies at 9 weeks gestation or later for aneuploidies of the following chromosomes: • 13 • 18 • 21 • X • Y **This includes the following indications:** • As follow-up to abnormal maternal serum screen results when diagnostic testing is declined • Pregnancies with multiple anomalies **AND** diagnostic testing is not possible **Explanation of change** Clarifications • Combined "Sex prediction for pregnancies at risk for an X-linked disorder" with below as an exception under NMN list • Expanded criteria to include follow-up screening for abnormal maternal serum screen results in viable singleton/twin pregnancies when diagnostic testing is declined and screening for pregnancies with multiple anomalies when diagnostic testing is not possible	November 17, 2024
The use of cfDNA screening is considered not medically necessary for clinical scenarios including, but not limited to, the following:	**Not Medically Necessary:** The use of cfDNA screening is considered not medically necessary for clinical scenarios including, but not limited to, the following: • Higher order gestations (≥3 fetuses) • Fetal demise • Co-twin demise (vanishing twin) • Multiple fetal anomalies • Concurrent screening with other maternal serum biomarkers • Prior to 9 weeks gestation The use of cfDNA screening is considered not medically necessary when screening for the following: • Sex only (without family history of an X-linked disorder) • Single genes (e.g., CFTR, HBB, SMN1, RhD) • Microdeletions (e.g., DiGeorge syndrome, Cri-du-chat syndrome) • Twin zygosity (monozygotic versus dizygotic) • Genome-wide copy number variants • Aneuploidies of other autosomal chromosomes, e.g., trisomy 7, trisomy 15, trisomy 16, trisomy 22, etc. • Polygenic risk assessment	November 17, 2024

	Note: Some of the tests listed above have a role in care under certain circumstances, but they should not be routinely offered. **Explanation of change** Clarifications Combined above "Sex prediction for pregnancies at risk for an X-linked disorder" with exception "Sex only (without family history of an X-linked disorder)" under NMN list	

Carelon Guideline	Policy Change Summary	Effective Date
Somatic Testing of Solid Tumors		
Metastatic or Advanced Cancer (Tumor change to Tissue Agnostic Testing)		
Tissue-agnostic testing for patients with advanced solid tumors	**Tissue-agnostic testing for patients with advanced solid tumors** Multi-gene panel testing is considered medically necessary when **ALL** of the following are true: • The individual has a metastatic or advanced solid tumor and adequate performance status for cancer treatment • A genomic biomarker-linked therapy has been approved by the FDA for the individual's specific clinical scenario, or there are established genomic biomarker-based treatment contraindications or exclusions • There are no existing indications for the planned therapy such that its use does not depend on the results of genetic testing (i.e., immune checkpoint inhibitor indications) • There are no satisfactory tumor-specific standard therapies available • Testing falls into ANY of the following categories: ○ Mismatch-repair (MMR) deficiency ▪ MLH1, MSH2, MSH6, PMS2 or EPCAM genes by PCR or NGS testing ▪ Microsatellite testing (MSI) and/or dMMR testing ▪ MLH-1 promoter methylation and/or BRAF V600E mutation testing with nuclear expression loss of MLH1 and PMS2 by immunohistochemistry ○ Tumor mutational burden (TMB) testing as determined by an FDA-approved test with reporting using the threshold of ≥10 mutations/megabase (mut/Mb) ○ NTRK and RET fusion testing ○ BRAF V600E mutation testing **Explanation of change** Added clarification about TMB testing by FDA-approved test with reporting threshold ≥ 10 mutations/megabase (mut/Mb)	November 17, 2024
	Cancer-specific Criteria	
Bladder Cancer (Urothelial Carcinoma, including the Upper Tract)	Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing for FGFR variants is considered medically necessary for individuals with urothelial tumors of the bladder or upper urinary tract when **ALL** of the following criteria are met: • The individual has biopsy-proven urothelial malignancy • The urothelial malignancy is locally advanced (stage IIIB), recurrent, or metastatic (stage IV)	November 17, 2024

	• The individual is a potential candidate for an FDA-approved targeted therapy prescribed on the basis of the FGFR test result • The individual has not had prior FGFR testing in the locally advanced, recurrent, or metastatic setting Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR), or mismatch repair deficiency (dMMR by IHC) is considered medically necessary when BOTH of the following criteria are met: • The individual has biopsy-proven urothelial carcinoma of the bladder or upper urinary tract. • The individual has not had prior MSI or dMMR testing Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details. **Explanation of change** Clarification about prior FGFR testing Expansive changes for microsatellite instability/mismatch repair deficiency (MSI/dMMR)	
Brain Cancer (Malignant Glioma)	Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered medically necessary for individuals with malignant gliomas of the brain when **ALL** of the following criteria are met: • The individual has biopsy-proven, primary malignant glioma of the brain • Genetic testing includes at least the following: ○ BRAF V600E ○ IDH1 and IDH2 • The individual has not had prior testing for these genes Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) or mismatch repair deficiency (dMMR by IHC) is considered medically necessary when **ALL** of the following criteria are met: • The individual has biopsy-proven, malignant glioma of the brain • The individual is under age 50 years and IDH wild type • The individual has not had prior MSI or dMMR testing **Explanation of change** New clinical scenario considered clarifications for what may have otherwise been reviewed using general (umbrella) criteria	November 17, 2024
Breast Cancer, Metastatic	Testing of tumor tissue for somatic pathogenic variants of PIK3CA, AKT1, PTEN, and ESR1 is considered medically necessary for postmenopausal females and adult males when **ALL** of the following criteria are met:	November 17, 2024

	• The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for treatment per FDA-label with alpelisib or capivasertib plus fulvestrant, AND/OR the individual is a candidate for treatment per FDA label with elacestrant • The individual has not had prior testing (via circulating cell-free DNA testing or tissue-based testing) for the targeted gene(s) of interest in the metastatic setting *Note: Cell-free DNA testing (liquid biopsy) guideline criteria may apply; see Cell-free DNA Testing guidelines. Also, tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details.* **Explanation of change** Expanded breast cancer criteria to include a wider scope of testing for metastatic disease: AKT1 and PTEN (related to capivasertib/fulvestrant therapy)	
Cholangio-carcinoma (Biliary Tract Cancers)	Tissue-based somatic tumor testing for pathogenic variants in individuals with cholangiocarcinoma is considered medically necessary when **ALL** of the following criteria are met: • The individual has biopsy-proven cholangiocarcinoma • The cholangiocarcinoma is locally advanced, unresectable, or metastatic • The panel testing to include analysis of pathogenic variants in these genes: IDH1, FGFR, and BRAF • The individual is a potential candidate for FDA-approved targeted therapy prescribed on the basis of the panel test results • The individual has not had prior somatic tumor testing for IDH1, FGFR, and BRAF in the metastatic setting *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details.* **Explanation of change** Clarified language around specific pathogenic variants for which testing is indicated	November 17, 2024
Colorectal Cancer, Localized and Metastatic	**Universal testing for all patients with newly diagnosed localized or metastatic colorectal cancer** Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) or mismatch repair deficiency (dMMR by IHC) is	November 17, 2024

	considered medically necessary when **BOTH** of the following criteria are met: ▪ The individual has biopsy-proven adenocarcinoma of the colon or rectum ▪ The individual has not had prior MSI or dMMR testing **Localized colorectal cancer** Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered medically necessary for individuals with localized (stage II-III) colorectal cancer when BOTH of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the colon or rectum • Includes ANY or ALL of the following, with no prior testing ○ MSI testing by PCR and/or dMMR IHC testing ○ BRAF V600E ○ KRAS ○ MLH-1 promoter methylation (applicable when there is nuclear expression loss of MLH1 and PMS2 by IHC) *See Hereditary Cancer Testing guideline for further details regarding indications for germline MMR testing.* **Explanation of change** Expanded criteria for MSI/dMMR testing to allow in individuals with de novo metastatic disease, whereas current criteria would have allowed it in localized disease or refractory metastatic disease (as per tumor agnostic guidelines)	
Metastatic colorectal cancer	**Metastatic colorectal cancer** Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered medically necessary for individuals with recurrent or metastatic colorectal cancer and may be performed on the primary tumor or a metastatic site when **ALL** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the colon or rectum • Assessment includes ANY or ALL of the following: ○ POLE/POLD1 mutations ○ Extended RAS testing (KRAS and NRAS exons 2,3, and 4) ○ BRAF V600E ○ HER2 amplification testing ○ MLH-1 promoter methylation (applicable when there is nuclear expression loss of MLH1 and PMS2 by IHC) • There has been no prior testing for these molecular aberrations *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details.* **Explanation of change**	November 17, 2024

	Expanded POLE/POLD1 testing because now it could be invoked as a reason for repeat testing, if necessary, if it was not included in testing as per prior guideline criteria Clarifications	
Endometrial Carcinoma (removed "Advanced")	Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) or mismatch repair deficiency (dMMR by IHC) is considered medically necessary when BOTH of the following criteria are met: • The individual has biopsy-proven endometrial carcinoma • The individual has not had prior MSI or dMMR testing Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered medically necessary for individuals with endometrial carcinoma and may be performed on the primary tumor or a metastatic site when ALL of the following criteria are met: • The individual has biopsy-proven endometrial carcinoma • Assessment includes the following, as applicable: ○ MLH-1 promoter methylation (applicable when there is nuclear expression loss of MLH1 and PMS2 by IHC) ○ POLE mutation testing (NGS) ○ P53 mutation testing (NGS or IHC) • There has been no prior testing for these molecular aberrations *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details. Carelon Guidelines for Hereditary Cancer Testing* **Explanation of change** Expanded routine testing for MSI/dMMR; also expanded POLE and p53 testing Limited panel size	November 17, 2024
Melanoma, Advanced	Tissue-based somatic tumor testing for BRAF V600E pathogenic variant by validated IHC, PCR, or NGS methods for individuals with resectable or unresectable high-risk stage IIC, stage III or stage IV cutaneous melanoma is considered **medically necessary** when **BOTH** of the following criteria are met: • The individual has biopsy-proven cutaneous malignant melanoma • Prior testing has not been performed Tissue-based somatic tumor testing for individuals with resectable or unresectable high-risk stage IIC, stage III or stage IV melanoma that is BRAF V600E **wild-type or mucosal melanoma** is considered medically necessary when **ALL** of the following criteria are met: • The individual has biopsy-proven malignant melanoma • Prior testing has not been performed	November 17, 2024

	• Testing includes ANY or ALL of the following: ○ KIT variant testing ○ NRAS variant testing ○ Additional BRAF variant testing Testing of individuals with metastatic **uveal melanoma for HLA-A*0201** is considered **medically necessary** when **ALL** of the following criteria are met: • The individual has biopsy-proven uveal melanoma and evidence of metastatic disease • Prior testing for HLA-A*0201 has not been performed • The individual is a candidate for treatment with tebentafusp **Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details*. **Explanation of change** Minor wording changes to improve readability	
Non-Small Cell Lung Cancer, Localized (stage IB-IIIA)	Tissue-based somatic testing is considered **medically necessary** to identify EGFR pathogenic variant in individuals with localized NSCLC when **BOTH** of the following criteria are met: • Biopsy-proven, stage IB-IIIA NSCLC with **ANY** of the following characteristics: ○ An adenocarcinoma component on histology ○ Non-squamous, non-small cell histology ○ Squamous cell carcinoma histology when **ANY** of the following clinical features are present: ▪ Age 50 years or younger ▪ Those who never smoked cigarettes (<100 cigarettes in a lifetime) ▪ Those who quit smoking >15 years ago • Test results will determine candidacy for treatment with Osimertinib **Explanation of change** Clarifications about how light or absent tobacco exposure is defined	November 17, 2024
Non-Small Cell Lung Cancer, Metastatic Current guideline	Tissue-based NGS panel testing is considered **medically necessary** to identify pathogenic variants in individuals with stage IIIB, IIIC, or metastatic NSCLC when **ALL** of the following criteria are met: • Biopsy-proven NSCLC with **EITHER** of the following characteristics: ○ Any adenocarcinoma component on histology ○ Non-squamous, non-small cell histology ○ Squamous cell carcinoma histology when A**NY** of the following clinical features are present: ▪ Age 50 years or younger	November 17, 2024

	▪ Those who never smoked cigarettes (<100 cigarettes in a lifetime) ▪ Those who quit smoking >15 years ago • The multi-gene NGS panel testing contains, at minimum*, testing of appropriate molecular aberrations (mutations, rearrangements, fusions, or amplifications) in **ALL** of the following genes: EGFR, ALK, ROS1, BRAF, ERBB2 (HER2), KRAS, MET exon 14 skipping, NTRK, and RET • The individual is a candidate for targeted therapy that may be prescribed based on the panel test results • The individual has not had prior NGS testing in the metastatic setting, unless **BOTH** of the following are met: ○ There is evidence of disease progression while on EFGR-targeted therapy ○ Tissue biopsy of a progressing lesion is being used for additional testing **Testing may be more focused if other techniques (such as IHC or FISH) are simultaneously (or previously) used for specific genes listed in the criteria that are not also included on the multi-gene panel.* *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details.* **Explanation of change** New criteria for metastatic squamous cell carcinoma Allowance for repeat NGS testing in the setting of progressive disease, if a progressing lesion is being used for the repeat testing	
Ovarian Cancer (Epithelial)	Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing to determine HRD status by testing for pathogenic variants of BRCA1, BRCA2 with concomitant evaluation for genomic instability through an FDA approved test is considered **medically necessary** in individuals with locally advanced (stage III), metastatic (stage IV), or recurrent epithelial ovarian cancer when **ALL** of the following criteria are met: • The individual has biopsy-proven epithelial ovarian cancer • The individual does not have previously established pathogenic variants of BRCA 1 or BRCA2 through germline testing • The individual has not had prior testing that establishes HRD status in the locally advanced (stage III), metastatic (stage IV), or recurrent setting • The individual is a candidate for treatment with an FDA-approved PARP inhibitor Germline testing for pathogenic variants is considered medically necessary for all individuals with epithelial ovarian carcinoma. *See Hereditary Cancer Testing guideline for further details.*	November 17, 2024

	Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details. **Explanation of change** Clarifications regarding HRD testing and prior testing More restrictive to the extent that HRD testing must include evaluation of genomic instability through an FDA approved test	
Pancreatic Adenoca-rcinoma	Germline testing for pathogenic variants is considered **medically necessary** for all individuals with pancreatic adenocarcinoma. *See Hereditary Cancer Testing guideline for further details.* Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) or mismatch repair deficiency (dMMR by IHC) is considered **medically necessary** when BOTH of the following criteria are met: • The individual has biopsy-proven pancreatic adenocarcinoma • The individual has not had prior MSI or dMMR testing Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered **medically necessary** when **ALL** of the following criteria are met: • The individual has biopsy-proven locally advanced (stage III), metastatic (stage IV), or recurrent pancreatic adenocarcinoma • The NGS panel includes BRCA1, BRCA2, PALB2, KRAS, as applicable • The individual has not had prior NGS testing in the locally advanced, metastatic, or recurrent setting *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details.* ***Explanation of change*** *Added criteria for targeted (50 or fewer genes) somatic testing beyond MSI/dMMR in locally advanced, metastatic, or recurrent pancreatic adenocarcinoma*	November 17, 2024
Prostate Cancer, Metastatic	Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) or mismatch repair deficiency (dMMR by IHC) is considered **medically necessary** when **BOTH** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the prostate • The individual has not had prior MSI or dMMR testing Tissue-based NGS panel testing is considered **medically necessary** to identify pathogenic variants in individuals with	November 17, 2024

	metastatic prostate cancer when **ALL** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the prostate • The individual is a candidate for ONE of the following therapies: ○ FDA-approved PARP inhibitor (olaparib, rucaparib, or another PARP inhibitor approved for use in this setting) ○ FDA-approved PD-1 inhibitor (pembrolizumab or another checkpoint inhibitor approved for use in this setting) • The NGS panel includes BRCA2, BRCA1, and may also include other genes encoding molecules involved in homologous recombination DNA damage repair (DDR), such as ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PABLB2, RAD51B, RAD51C, RAD51D, and RAD54L • The individual has not had prior NGS testing in the metastatic setting Germline testing for pathogenic variants is considered **medically necessary** for all individuals with metastatic prostate adenocarcinoma. *See Hereditary Cancer Testing guideline for further details.* *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tissue Agnostic Testing guideline for details.* **Explanation of change** Mostly clarification for MSI/dMMR testing; specified appropriateness of MSI/dMMR testing is in metastatic prostate cancer Moved ATM from required to "may be included" genes in approvable NGS panels Clarified the HRD genes which may be in panels in addition to BRCA testing	
Thyroid Cancer	**Testing of indeterminate thyroid nodules (ITN)** Use of next-generation gene expression classifier testing from fine needle aspirate sampling of a thyroid nodule is considered **medically necessary** when **ALL** of the following criteria are met: • There has been no prior testing of the same thyroid nodule • Initial cytopathology is reported as **ANY** of the following (Bethesda III or IV) categories: ○ Atypia of undetermined significance (AUS) ○ Follicular lesion of undetermined significance (FLUS) ○ Suspicious for follicular neoplasm (SFN) ○ Follicular neoplasm (FN) • The ITN is <4 cm in size **AND** does **NOT** have findings highly suspicious for malignancy on ultrasound (American Thyroid	November 17, 2024

	Association high suspicion pattern or American College of Radiology TIRADS 5) • **ONE** of the following gene expression classifiers may be used when performed as a stand-alone classifier test: ○ ThyGeNEXT/ThyraMIR multiplatform test ○ ThyroSeq Genomic Classifier ○ Afirma GSC **Explanation of change** Afirma GSC added as a gene expression classifier that may be used Clarifications	
Somatic genetic testing of thyroid malignancy	**Somatic genetic testing of thyroid malignancy** Tissue-based somatic tumor testing is considered **medically necessary** for individuals with advanced thyroid carcinoma that is not amenable to radioactive iodine therapy when the following criteria* are met: • The individual has biopsy proven unresectable, locally advanced, recurrent, or metastatic thyroid carcinoma or anaplastic thyroid carcinoma (any stage) • The testing includes assessment for pathogenic variants of BRAF V600E, ALK, NTRK, and RET • The individual is considered a potential candidate for FDA-approved oral targeted therapy based on the results of this testing **See additional guidelines concerning tissue agnostic somatic testing or hereditary cancer risk testing depending on the clinical scenario.* **Explanation of change** Modified language so that BRAF V600E, ALK, NTRK, and RET testing can be done in anaplastic thyroid cancer at any stage, or in unresectable, locally advanced, recurrent, or metastatic thyroid cancer	November 17, 2024

Carelon Guideline	Policy Change Summary	Effective Date
Somatic Testing of Hematologic Malignancies		
Acute Lymphocytic Leukemia	Tissue- (OR bone marrow-) based (OR alternatively, peripheral blood if morphologically detectable circulating blasts) somatic genetic testing (50 or fewer genes) is considered **medically necessary** for children or adults with acute lymphoblastic leukemia (**ALL**) when the following criterion are met: • Testing is for the purpose of establishing the diagnosis, to stratify risk, or to identify actionable therapeutic targets • A multi-gene panel contains genes that are identified with B-ALL or T-ALL, such as ABL1, ABL2, CRLF2, CSF1R, FLT3, FGFR, NTRK, LYN, PTK2Br, IL7R, JAK1, JAK2, JAK3, ETV6, RUNX1, TCF3, TCF4, PBX1, DUX4, PAX5, KMT2A, HLF, ZNF384, MEF2D, ZNF384, MYC, PDGFRB, SH2B3, TP53, IKZF1, NUTM1, MEF2D, ZNF384, RAS, PTEN, NOTCH1, and FBXW7 Chromosomal analyses of bone marrow specimens (or alternatively, peripheral blood if morphologically detectable	November 17, 2024

	circulating blasts), which may also include FISH testing, to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for children and adults with ALL. The use of NGS testing on bone marrow specimen is considered **medically necessary** in children or adults with ALL to measure minimal residual disease (MRD) at the end of initial treatment induction and end of initial consolidation and at similar defined points over the course of sequential therapies. BCR-ABL kinase domain point mutation analysis is considered **medically necessary** in the evaluation of individuals with BCR-ABL (Philadelphia chromosome) positive ALL to evaluate treated individuals who manifest suboptimal response to initial tyrosine kinase inhibitor therapy or loss of response to tyrosine kinase inhibitor therapy. PCR testing for BCR-ABL1 quantification on bone marrow specimen is considered **medically necessary** in the monitoring of Philadelphia chromosome-positive ALL. **Explanation of change** Clarifications. Statement about NGS testing on bone marrow specimen may be slightly restrictive, as it specifies time points where testing is appropriate (end of initial induction, end of initial consolidation, etc.)	
Acute Myelogenous Leukemia	Tissue-based (OR alternatively, peripheral blood if morphologically detectable circulating blasts) somatic genetic testing (50 or fewer genes) is considered medically necessary for individuals with acute myelogenous leukemia (AML) when the following criterion are met: • Testing is for the purpose of establishing the diagnosis, to stratify risk, or to identify actionable therapeutic targets • A multi-gene panel contains genes that are identified with AML, such as FLT3, IDH1, IDH2, NPM1, CBFB, MYH1, CEBPA, MLLT3, KMT2A, DEK, NUP214, KAT6A, CREBBP, GATA2, EVI1, DDX41, TP53, ASXL1, BCOR, EZH2, RUNX1, SF3B1, SRSF2, STAG2, U2AF1, and ZRSR2 Chromosomal analyses of preferred bone marrow specimens, which may also include FISH testing, to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for individuals with AML. The use of multi-gene panel NGS testing on peripheral blood or bone marrow specimens is considered **not medically necessary** in members with AML to measure minimal residual disease (MRD). The use of focused testing of peripheral blood or bone marrow using RT-qPCR is considered **medically necessary** to measure minimal residual disease (MRD) in acute promyelocytic leukemia, or NPM1 or core binding factor AML when used at appropriate	November 17, 2024

	defined points over the course of therapy such as at the end of initial treatment induction, at the end of initial consolidation, or at the completion of other sequential therapies. **Explanation of change** Clarifications (bulleted criteria) Added an indication for focused testing using RT-qPCR to measure minimal residual disease (MRD)	
Chronic Myeloid Leukemia	PCR testing for BCR-ABL1 quantification is considered **medically necessary** for response assessment every 3 months during active treatment with tyrosine kinase inhibitor therapy. PCR testing for BCR-ABL1 quantification is considered medically necessary for monitoring patients who have undergone discontinuation of tyrosine kinase inhibitor therapy with assessment not more frequent than the following schedule: monthly for the first 6 months after discontinuation, bimonthly for months 7-12, and every 3 months thereafter. **Explanation of change** Modified the timing for BCR-ABL1 quantification for monitoring in the first year after completion of tyrosine kinase inhibitor (TKI) therapy Added allowance for BCR-ABL1 quantification for monitoring patients at 3-month intervals beyond one year after completion of TKI therapy	November 17, 2024
Myeloproliferative Neoplasms	Bone marrow tissue-based **OR** peripheral blood somatic genetic testing (50 or fewer genes) is considered **medically necessary** for initial evaluation of suspected myeloproliferative neoplasms (MPN) (e.g., essential thrombocytosis, polycythemia vera, chronic neutrophilic leukemia, and primary myelofibrosis) **BOTH** of the following criteria are met: • PCR, FISH, or NGS testing is targeting applicable JAK2, CALR, CSF3R, and MPL genes for diagnostic workup and (if applicable) a focused set of additional genes for initial risk stratification in the event that a specific myeloproliferative neoplasm is diagnosed • **ONE** of the following clinical scenarios: ○ Hemoglobin ≥16.5 g/dL in male and hemoglobin ≥16.0 g/dL in female ○ Hematocrit greater than 49% in male and hematocrit greater than 48% in female ○ Platelet count ≥450 X 109/L ○ Leukocytosis (white blood cell) ≥11 X 109/L **Explanation of change** Added allowance for additional focused testing for initial risk stratification if a specific myeloproliferative neoplasm is diagnosed on initial diagnostic workup	November 17, 2024
Myelodysplastic Syndrome	Somatic testing (i.e., 50 or fewer genes) of bone marrow tissue **OR** peripheral blood is considered **medically necessary** for individuals with clinically diagnosed or suspected myelodysplastic syndrome when **BOTH** of the following criteria are met: • Testing is for the purpose of establishing the diagnosis, to stratify risk, or to identify actionable therapeutic targets	November 17, 2024

	• A multi-gene panel contains genes that are identified with MDS, such as ASXL1, DNMT3A, EZH2, NRAS, RUNX1, SF3B1, SRSF2, STAG2, TET2, TP53, U2AF1, ZRSR2, and UBA1 Chromosomal analyses of preferred bone marrow specimens to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for individuals with myelodysplastic syndrome. **Explanation of change** Clarified that testing can be pursued for diagnosis or risk stratification and clarified the list of genes that may be associated with MDS	

New 2024 Category III CPT Codes

All category III CPT Codes, including new 2024 codes, are **non-covered** unless they are explicitly described as "medically necessary" in a BCBSMA medical policy. To search for a particular code, click the following link:

https://www.bluecrossma.org/medical-policies/
and type the code in the search box on the page. Consult the coverage statement of any associated medical policy. ***If there is no associated policy, the code is non-covered*.**

A full draft version of each policy is available only by request, to ordering participating clinician providers, one month prior to the effective date of the policy. To request draft policies, contact Medical Policy Administration at ebr@bcbsma.com.

Definitions

Medically Necessary: Procedure, services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.

Edits: Blue Cross Blue Shield of Massachusetts uses edits to enforce medical policies. These system edits use CPT/HCPCS and ICD-10 diagnosis codes to ensure claims are processing according to the medical policy.

Post Payment Review: After a claim has been paid, Blue Cross Blue Shield of Massachusetts will review the paid claim and determine if the claim has been paid appropriately.

Prior Authorization: Certain inpatient and outpatient services are reviewed to determine if they are medically necessary and appropriate for the member. If the determination is made that the services are medically necessary, an approval—or authorization— is sent in writing to the member, primary care provider (PCP), the treating physician, and the facility, if applicable, to let them know that the services have been approved.