MASSACHUSETTS

MEDICAL POLICY ANNOUNCEMENTS

Posted December 2023

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

Anesthesiology
Cardiology
Gastroenterology
Neurology
Obstetrics Gynecology
Orthopedics
Pharmacy
Primary Care Medicine; Laboratory
Radiology
Vascular Surgery

Carelon Clinical Appropriateness Guidelines
Genetic Testing
- Prenatal Testing
- Cell-free DNA Testing for Cancer
- Somatic Tumor Testing
- Somatic Testing of Hematologic Malignancies

Radiology
- Cardiac Imaging
- Oncologic Imaging
- Brain Imaging
- Head and Neck Imaging
- Chest Imaging
- Abdomen and Pelvis Imaging

Radiation Oncology
- Intensity modulated radiation therapy (IMRT) for Colon Cancer
- Stereotactic Body Radiation Therapy (SBRT) for Hepatocellular Carcinoma
- External Beam Radiation (EBRT)/IMRT for Prostate Cancer

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

ANESTHESIOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED

Monitored Anesthesia Care (MAC)	154	**Policy clarified.** American Society of Anesthesiology (ASA) Physical Status Classification examples added. The list of risk factors or significant medical conditions guidelines clarified. **Policy clarified** to include 2023 UpToDate® information on screening for colorectal cancer in patients with a family history of colorectal cancer or advanced polyp. Clarified coding information. **Enforcement update** Covered diagnoses codes list added to the policy. New diagnoses-to-CPT codes edit to be implemented on January 1, 2024.	January 1, 2024	Commercial Medicare	Prior authorization **is still not required.**

CARDIOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Radio-frequency Ablation of the Renal Sympathetic Nerves as a Treatment for Uncontrolled Hypertension	919	**Policy clarified.** The indication for resistant hypertension was removed and changed to: Individuals with uncontrolled hypertension, despite the use of anti-hypertensive medications or who poorly tolerate blood pressure therapy, who receive radiofrequency ablation of the renal sympathetic nerves. Policy statement remains investigational.	December 1, 2023	Commercial Medicare	No action required.

GASTROENTEROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Fecal Calprotectin Testing	329	**Policy revised.** Medically necessary indications described. 83993 Calprotectin, fecal	March 1, 2024	Commercial Medicare	No action required.
Medical Technology Assessment Investigational (Non-Covered) Services List	400	**Policy revised.** CPT code 83631 Lactoferrin, fecal; quantitative removed from the non-covered list.	March 1, 2024	Commercial Medicare	No action required.
Monitored Anesthesia Care (MAC)	154	**Policy clarified.** American Society of Anesthesiology (ASA) Physical Status Classification examples added. The list of risk factors or significant medical conditions guidelines clarified. **Policy clarified** to include 2023 UpToDate® information on screening for colorectal cancer in patients with a family history of colorectal cancer or advanced polyp. Clarified coding information. **Enforcement update** Covered diagnoses codes list added to the policy. New diagnoses-to-CPT codes edit to be implemented on January 1, 2024.	January 1, 2024	Commercial Medicare	Prior authorization **is still not required.**

NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED

Remote Electrical Neuromodula-tion for Migraines	145	**Policy revised.** Remote electrical neuromodulation for prevention of migraine is considered investigational.	March 1, 2024	Commercial Medicare	No action required.

OBSTETRICS GYNECOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Gender Affirming Services (Transgender and Gender Diverse Services)	189	**Policy revised** to remove orchiectomy and hysterectomy procedure codes. Prior authorization is not required for the following codes: Orchiectomy codes 54520; 54690 Hysterectomy codes 58150; 58180; 58260 58262; 58275; 58290 58291; 58541; 58542 58543; 58544; 58550 58552; 58553; 58554 58570; 58571; 58572 58573	December 1, 2023	Commercial Medicare	No action required.

ORTHOPEDICS

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Suture Button Suspension-plasty Fixation System for Thumb Carpometa-carpal Osteoarthritis	031	**New medical policy** describing investigational indications. Suture button suspensionplasty for thumb carpometacarpal joint osteoarthritis is considered investigational.	March 1, 2024	Commercial Medicare	No action required.

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions	374	**This policy will be retired.** InterQual criteria will be used to determine coverage for this procedure.	March 1, 2024	Commercial Medicare	Prior authorization is still required. Submit prior authorization requests using Authorization Manager.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
BCBSMA will be adding select low cost biosimilars to Humira on the formulary. By adding these low cost biosimilars, we will expand choice for our members with inflammatory conditions and the providers managing these patients. We will continue to cover Humira in addition to biosimilars below.					
Immune Modulating Drugs	004	**Humira Biosimilars** **Preferred Specialty tier and Preferred in policy** ▪ Humira ▪ Hadlima ▪ Yusimry ▪ Amjevita **(up until 4/1/2024)** **Non-Preferred Specialty Tier and Non-Preferred in Policy** ▪ Adalimumab-adbm ▪ Adalimumab-adaz ▪ Adalimumab-fkjp ▪ Hyrimoz (Cordavis product) **Non-Covered Specialty and Non-Preferred in Policy** ▪ Amjevita **(after 4/1/2024)** ▪ Cyltezo ▪ Hyrimoz ▪ Idacio ▪ Yuflyma **REMICADE** **Effective 4/1/2024**, we will be moving Remicade to a non-covered position.	January 1, 2024	Commercial Medicare	Prior authorization is still required.

		We will continue to cover Inflectra and Avsola as preferred alternatives with Renflexis and Infliximab as non-preferred alternatives to Remicade.			

PRIMARY CARE MEDICINE; LABORATORY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Vitamin D Assay Testing	746	**Reminder** Frequency claim edits will be added to reinforce the policy. Claims will process according to the policy and reduce the number of claims that need post-payment review. **Repeat Testing** Once a patient is identified as vitamin D deficient, further testing may be medically necessary to ensure there has been adequate replacement. If the patient is not vitamin D deficient, repeat testing is not medically necessary.	January 1, 2024	Commercial	No action required.
Laboratory Testing Investigational Services	165	**Policy clarified.** Ongoing investigational codes 0376U, 0384U, 0385U, were transferred from MP #400 Non-covered services list to MP #165. These tests are considered investigational. There are no assigned specific codes: ▪ Prometheus® IBD sgi Diagnostic®	December 1, 2023	Commercial Medicare	No action required.

		▪ Prometheus® Crohn's Prognostic ▪ know error® Codes 0368U, 0380U, 0405U, 0410U are managed by Carelon. Prior authorization is required from Carelon.			

RADIOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Carelon Advanced Imaging Radiology CPT and HCPCS Codes	900	**Policy revised.** Code C9156 Flotufolastat f 18, diagnostic, 1 millicurie added.	March 1, 2024	Commercial Medicare	Prior authorization is required through Carelon.

VASCULAR SURGERY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment Investigational (Non-Covered) Services List	400	**Policy revised**. CPT codes 36836 and 36837 fistula creation codes removed from non-covered list.	March 1, 2024	Commercial Medicare	No action required.

Carelon Clinical Appropriateness Guidelines

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

Prenatal Testing
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
Prenatal Testing using cell free DNA	**Genetic counseling** The approach chosen for any prenatal screening technique should involve shared decision-making between the patient and the clinician. Counseling is encouraged prior to any prenatal screening that involves cell-free DNA testing and should include **ALL** of the following components: • Clearly defined differences between screening and diagnostic prenatal genetic testing • Risk assessment for and education about aneuploidies • Counseling to promote informed choices and adaptation to the risk or presence of a genetic condition • Counseling for the psychological aspects of genetic testing Note: Post-test counseling should be performed for any positive or nonreportable cfDNA screen result. **Explanation of change:** Clarification **Viable singleton or twin pregnancy** Prenatal testing using cell-free DNA (cfDNA) is considered **medically necessary** as a screening test in viable singleton or twin pregnancy at 9 weeks gestation or later for **ANY** of the following chromosomal abnormalities: • Trisomy 13 • Trisomy 18 • Trisomy 21 • Sex chromosome aneuploidies affecting the X or Y chromosome **AND/OR** • Sex prediction for pregnancies at-risk for an X-linked disorder **Explanation of change:** Clarification	March 17, 2024

Cell-free DNA Testing for Cancer
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 locally advanced (stage IIIb), recurrent, or metastatic non-small cell lung cancer** Liquid (ctDNA) based testing is considered **medically necessary** for individuals with pathologically confirmed locally advanced (stage IIIb), recurrent, or metastatic non-small cell lung cancer (NSCLC), and **ALL** of the following criteria are met:	March 17, 2024

	• There is insufficient tumor tissue available for NGS-based somatic profiling or for whom tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition • No prior NGS-based somatic profiling test has previously been performed for this pathological diagnosis of NSCLC • The test is being used to provide genetic information related to the current set of actionable mutations recognized by ASCO guidelines to inform management at diagnosis or treatment progression on or after chemotherapy or immunotherapy **Explanation of change:** Clarification **Individuals with metastatic breast cancer who may benefit from PIK3CA or ESR1-targeted therapy** Liquid (ctDNA) based testing, to include PIK3CA and/or ESR1 somatic tumor testing, is considered **medically necessary** to identify individuals who may benefit from the use of alpelisib or elacestrant, respectively (or other FDA-approved targeted agent) 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 an applicable FDA-approved targeted agent • The individual has not had prior testing for the targeted gene 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:** Clarification **Individuals with metastatic adenocarcinoma of the prostate who may benefit from a PARP inhibitor or PD-1 inhibitor** Liquid (ctDNA) based testing is considered **medically necessary** for individuals with metastatic adenocarcinoma when **ALL** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the prostate • The individual has not had prior NGS testing in the metastatic setting ◦ The individual is a candidate for **ONE** of the following therapies: ▪ FDA-approved PARP inhibitor (olaparib, rucaparib, or other approved PARP inhibitor) ▪ FDA-approved PD-1 inhibitor (pembrolizumab, or other approved checkpoint inhibitor) • 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:** Clarification	

Somatic Tumor Testing

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
Umbrella Criteria – same for solid tumors and hematologic malignancies		
Somatic Genomic Testing (Tumor Biomarker Testing)	Somatic genomic testing is considered **medically necessary** in individuals with cancer when **ALL** of the following criteria are met: • The genomic testing has established analytical and clinical validity (i.e., FDA-approved test, when available) and is performed in an appropriately certified laboratory • The genetic test has established clinical utility such that a positive or negative result will meaningfully impact the clinical management (predictive, diagnostic, prognostic, or therapeutic) of the individual and will likely result in improvement in net health outcomes (i.e., the health benefits of the interventions outweigh any medical or psychological harmful effects of the testing intervention) • When there are genomic biomarker-linked therapies approved by the U.S. Food and Drug Administration (FDA) for the individual's specific cancer scenario and such therapies are being considered in the near term • When considering a treatment for which there are specific genomic biomarker-based contraindications or exclusions related therapeutic decisions being considered in the near term ○ Clinical decision making incorporates the known or predicted impact of a specific genomic alteration on protein expression or function and published clinical data on the efficacy of targeting that genomic alteration with a particular agent **Explanation of change:** Clarification	March 17, 2024
Somatic Testing of Solid Tumors Metastatic or Advanced Cancer (Tumor Agnostic Testing)		
Tumor 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 their cancer 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	March 17, 2024

	▪ 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 ○ NTRK and RET fusion testing ○ BRAF V600E mutation testing **Explanation of change:** Clarification. Removed "FDA-approved" under MMR deficiency (covered by the Umbrella Criteria now).	
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 or metastatic • 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 metastatic setting Tissue-based somatic tumor testing for microsatellite instability (MSI testing, to include dMMR IHC) is considered **medically necessary** for individuals with muscle-invasive urothelial tumors of the upper urinary tract. *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 Tumor Agnostic Testing guideline for details.* **Explanation of change:** Restrictive (number of genes), Clarifications	March 17, 2024
Breast Cancer	**Localized breast cancer** Gene expression profiling is considered **medically necessary** for individuals with localized breast cancer using Oncotype DX, MammaPrint, EndoPredict, Prosigna Breast Cancer Prognostic Gene Signature Assay, or the Breast Cancer Index when **ALL** of the following criteria are met: • [No change to criteria] Gene expression profiling with the Oncotype DX or MammaPrint is considered **medically necessary** for postmenopausal females and adult males (referring to the sex assigned at birth) with 1 to 3 positive axillary lymph nodes (pN1a, pN1b or pN1c) when **ALL** of the following criteria are met: • Surgery has been performed and a full pathological evaluation of the specimen has been completed • Histology is ductal, lobular, mixed, or metaplastic	March 17, 2024

	• Receptor status is estrogen receptor positive (ER+), progesterone receptor positive (PR+), or both; **AND** HER2-negative • Chemotherapy is being considered by the individual and their provider • No other breast cancer gene expression profiling assay has been conducted for this tumor (including testing on any metastatic foci or on other sites when the tumor is multifocal) **Explanation of change:** Clarification to include all individuals in this clinical setting referring to the sex assigned at birth (females or males) **Metastatic breast cancer** Testing for somatic pathogenic variants of PIK3CA is considered **medically necessary** for postmenopausal females and adult males when **ALL** of the following criteria are met: • The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for alpelisib or another FDA-approved PIK3CA-targeted agent • The individual has not had prior testing for PIK3CA in the metastatic setting Testing for somatic pathogenic variants of ESR1 is considered **medically necessary** for postmenopausal females and adult males when **ALL** of the following criteria are met: • The individual has ER-positive and HER-negative metastatic breast cancer • The individual is a candidate for treatment for elacestrant per the FDA label • The individual has not had prior testing for ESR1 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 **Tumor Agnostic Testing** guideline for details. **Explanation of change:** Clarification	
Cholangiocarcinoma (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 is inclusive of the following pathogenic variants: 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 in the metastatic setting	March 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 Tumor Agnostic Testing guideline for details. **Explanation of change:** Clarifications. Added FDA-approved to therapy.	
Colorectal Cancer	**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 and/or dMMR IHC testing ○ BRAF V600E variant (RAS variants may also be part of some targeted panels) ○ MLH-1 promoter methylation and/or BRAF V600E mutation testing with nuclear expression loss of MLH1 and PMS2 by immunohistochemistry **Explanation of change:** Expansive (RAS variant add), Restrictive (number of genes), Clarification **Metastatic colorectal cancer** Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered **medically necessary** for individuals with 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: ○ MSI testing and/or dMMR IHC testing ○ Extended RAS testing (KRAS and NRAS variants) ○ BRAF V600E variant ○ HER2 testing ○ MLH-1 promoter methylation and/or BRAF V600E mutation testing with nuclear expression loss of MLH1 and PMS2 by immunohistochemistry • There has been no prior 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 Tumor Agnostic Testing guideline for details.* **Explanation of change**: Restrictive (number of genes), Clarification	March 17, 2024

Endometrial Carcinoma, Advanced	Tissue-based somatic tumor testing is considered **medically necessary** for individuals with advanced 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: ○ MSI-H and/or Dmmr mismatch repair testing ○ MLH-1 promoter methylation testing with IHC nuclear expression loss of MLH1 and PMS2 • There has been no prior 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 Tumor Agnostic Testing guideline for details. Additionally, for MLH1 germline testing for Lynch Syndrome, please refer to the Hereditary Cancer Testing guideline.* **Explanation of change**: Clarification. Removed "FDA-approved" (covered by the Umbrella Criteria now).	March 17, 2024
Melanoma	**Diagnostic and prognostic testing in melanoma** Gene expression profiling of suspected or established cutaneous, mucosal, or uveal melanoma for diagnosis or prognostication is considered **not medically necessary** **Explanation of change**: Clarification **Somatic tumor testing in advanced melanoma** Tissue-based somatic tumor testing for **BRAF V600E** pathogenic variant by validated IHC, PCR, or NGS methods for individuals with resectable or unresectable stage III or stage IV cutaneous melanoma or high-risk stage IIC 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 stage III or stage IV melanoma or high-risk stage IIC 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 • 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** using is considered **medically necessary** when **ALL** of the following criteria are met:	March 17, 2024

	• 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 Tumor Agnostic Testing guideline for details.* **Explanation of change**: Clarifications. BRAF mutations are rare in uveal melanoma and not relevant in treating mucosal melanoma, so the BRAF testing is appropriately focused on cutaneous melanoma. To accommodate additional testing for mucosal melanoma (particularly KIT testing), mucosal melanoma is explicitly added here because those patients will generally not have been tested for BRAF V600E already.	
Ovarian Cancer (Epithelial)	Targeted (i.e., 50 or less genes) tissue-based somatic testing for pathogenic variants of BRCA1, BRCA2, and to determine HRD status in individuals with recurrent epithelial ovarian cancer is considered **medically necessary** when **ALL** of the following criteria are met: • The individual has biopsy-proven epithelial ovarian cancer • The individual is a candidate for treatment with an FDA-approved PARP inhibitor • The individual has not had prior testing for these genes in the metastatic setting Germline testing for pathogenic variants is considered **medically necessary** for all individuals with epithelial ovarian carcinoma. *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 Tumor Agnostic Testing guideline for details.* **Explanation of change:** Restrictive (number of genes), Clarification. Removed "FDA-approved complementary diagnostic test" (covered by the Umbrella Criteria now).	March 17, 2024
Pancreatic Adenocarcino-ma	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 testing, to include dMMR IHC) is considered **medically necessary** for individuals with locally advanced or metastatic pancreatic adenocarcinoma.	March 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 Tumor Agnostic Testing guideline for details. **Explanation of change**: Clarification	
Prostate Cancer	**Localized prostate cancer** Gene expression profiling and genomic biomarker tests as a technique for prostate cancer screening, detection, and management are considered **not medically necessary** for all indications. **Metastatic prostate cancer** Tissue-based NGS panel testing is considered **medically necessary** to identify pathogenic variants in individuals with 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 ATM, and may also include other genes encoding molecules involved in homologous recombination DNA damage repair (DDR) such as PALB2, FANCA, RAD51D, CHEK1/2, BARD1, and CDK12, among others • The individual has not had prior NGS testing in the metastatic setting Tissue-based somatic tumor testing for microsatellite instability (MSI testing, to include dMMR IHC) is considered **medically necessary** for individuals with locally advanced or metastatic prostate cancer. Germline testing for pathogenic variants is considered **medically necessary f**or 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 Tumor Agnostic Testing guideline for details.* **Explanation of change**: Clarification	March 17, 2024
Thyroid Cancer	**Testing of indeterminate thyroid nodules (ITN)**	March 17, 2024

	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 Association high suspicion pattern or American College of Radiology TIRADS 5) • **ONE** of the following gene expression classifiers will be used: ○ ThyGeNEXT/ThyraMIR multiplatform test ○ ThyroSeq Genomic Classifier **Explanation of change:** Restrictive (removed Afirma – no longer offer standalone assay that is considered medically necessary, and incorporated radiographic findings)	
Unknown Primary Site Cancer	Gene expression profiling and somatic genetic testing for individuals to predict the site of tumor origin (i.e., non-agnostic tissue testing) of cancer of unknown primary are considered **not medically necessary**. *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 Tumor Agnostic Testing guideline for details* . **Explanation of change:** Clarification	March 17, 2024
Somatic Testing of Hematologic Malignancies Cancer-specific criteria		
Acute Lymphocytic Leukemia	Tissue- (**OR** bone marrow-) based (**OR** alternatively, peripheral blood if morphologically detectable circulating blasts) somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for children and adults with acute lymphoblastic leukemia (ALL) to establish the diagnosis or to identify actionable therapeutic targets when **ANY** of the following criteria are met: • A multi-gene panel contains, at a minimum, the following genes: ABL1, ABL2, CRLF2, CSF1R, FLT3, IL7R, JAK1, JAK2, JAK3, PDGFRB, SH2B3, TP53, and IKZF1 Chromosomal analyses of bone marrow specimens (or alternatively, peripheral blood if morphologically detectable circulating blasts), which may also include FISH testing, to detect and characterize clonal chromosomal abnormalities that have important diagnostic,	March 17, 2024

	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** to detect or quantify measurable/minimal residual disease (MRD) in children or adults with ALL. 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**: Expansive (specimen-type), Restrictive (number of genes, specimen-type, MRD and BCR-ABL1 monitoring), Clarification	
Acute Myelogenous Leukemia	Tissue-based (OR alternatively, peripheral blood if morphologically detectable circulating blasts) somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for individuals with acute myelogenous leukemia (AML) to establish the diagnosis and to identify actionable therapeutic targets when **ANY** of the following criteria are met: • A multi-gene panel contains, at a minimum, the following genes: FLT3, IDH1, IDH2, NPM1 CEBPA, DDX41, TP53; ASXL1, BCOR, EZH2, RUNX1, SF3B1, SRSF2, STAG2, U2AF1, 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 **Explanation of change**: Expansive (specimen-type), Restrictive (number of genes), Clarification	March 17, 2024
Chronic Myeloid Leukemia	Bone marrow tissue-based **OR** peripheral blood somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for establishing the diagnosis of suspected chronic myelogenous leukemia (CML) when the following criterion is met: • PCR or FISH testing includes the evaluation of the BCR-ABL1 fusion gene BCR-ABL kinase domain point mutation analysis is considered **medically necessary** in the monitoring of CML in **ANY** of the following circumstances: • Evaluation of individuals with CML to evaluate treated individuals who manifest suboptimal response to tyrosine kinase inhibitor therapy indicated by: ○ Lack of a partial hematologic or cytogenetic response at 3 months or greater after treatment onset	March 17, 2024

	○ Less than a complete hematologic and cytogenetic response at 12 months ○ Disease progression to accelerated or blast phase Chromosomal analyses of 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 CML. PCR testing for BCR-ABL1 quantification is considered **medically necessary** for response assessment every 3 months during active treatment and every 6 weeks in the first year after treatment discontinuation. **Explanation of change:** Restrictive (number of genes), format change to emphasize only one type of specimen for testing	
Multiple Myeloma	**Gene expression profile tests** Gene expression profile tests for diagnostic evaluation, risk stratification, or management of multiple myeloma are **considered not medically necessary.** **Chromosomal analyses of bone marrow specimens** Chromosomal analyses of 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 multiple myeloma. The use of NGS testing of tumor DNA from bone marrow specimens to detect or quantify minimal residual disease (MRD) in individuals with myeloma is considered **medically necessary** under **EITHER** of the following circumstances: • MRD testing used prior to initiating new treatment intended to induce myeloma remission • MRD testing used to assess depth of response after a cycle of treatment intended to induce myeloma remission **Explanation of change:** Restrictive (specimen-type, MRD)	March 17, 2024
Myeloproliferative Neoplasms	Bone marrow tissue-based **OR** peripheral blood somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for establishing the diagnosis of suspected myeloproliferative neoplasms (MPN) (e.g., essential thrombocytosis, polycythemia vera, chronic neutrophilic leukemia, and primary myelofibrosis) when **BOTH** of the following criteria are met: • PCR, FISH, or NGS testing is targeting applicable JAK2, CALR, CSF3R, and MPL genes • **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	March 17, 2024

	• **Explanation of change:** Restrictive (number of genes), format change to emphasize only one type of specimen for testing	
Myelodysplastic Syndrome	Somatic testing (i.e., 50 or less genes) of bone marrow tissue **OR** peripheral blood is considered **medically necessary** for individuals with clinically diagnosed or suspected myelodysplastic syndrome when **ANY** of the following criteria are met: • Testing is for the purpose of establishing the diagnosis or to identify actionable therapeutic targets • A targeted multi-gene panel contains, at a minimum, the following genes: ASXL1, DNMT3A, EZH2, NRAS, RUNX1, SF3B1, SRSF2, STAG2, TET2, TP53, U2AF1, ZRSR2 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**: Expansive (specimen-type), Restrictive (number of genes), Clarification	March 17, 2024

Radiology 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

Cardiac Imaging
The following updates will apply to the Carelon Clinical Appropriateness Guidelines for Radiology. 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
	Cardiac CT	
Cardiomyo-pathy	**Cardiomyopathy** Cardiac CT is considered medically necessary in **ANY** of the following scenarios: • Evaluation of patients with suspected arrhythmogenic right ventricular dysplasia (ARVD) who have **ANY** of the following: o Severe right ventricular dysfunction on another cardiac imaging study o Precordial T wave inversion not associated with RBBB	April 14, 2024

	○ First-degree relative with established ARVD or unexplained sudden cardiac death at age younger than 35 years ○ Ventricular tachycardia or frequent PVCs (> 500 in 24 hours or > 30 per hour) [no change to remaining criteria] **Explanation of change:** Added specificity to establish the basis for the suspicion of ARVD. This change aligns with Cardiac MRI guidelines.	

Oncologic Imaging
The following updates will apply to the Carelon Clinical Appropriateness Guidelines for Radiology. 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
Cancer Screening		
Breast cancer screening	**Breast cancer screening** • Individuals known to have **ANY** of the following established genetic mutations: ○ ATM ○ BARD1 ○ CDH1 ○ CHEK2 ○ NF-1 ○ PALB2 ○ PTEN ○ RAD51C or RAD51D ○ STK11 (Peutz-Jeghers syndrome) **Explanation of change:** Addition of high-risk genetic mutations (NCCN alignment citing absolute risk of 20% or greater)	April 14, 2024
Lung cancer screening	**Lung cancer screening** Annual low-dose CT is indicated when **ALL** of the following criteria are met: • Age equal to or greater than 50 and less than or equal to 80 • 20 or greater pack-year history* of cigarette smoking (current smoker, or quit date within the past 15 years), or established asbestosis-related lung disease **Explanation of change:** Clarification of asbestos-related lung disease as risk factor independent of smoking, aligned with original intent.	April 14, 2024
Pancreatic cancer screening	**Pancreatic cancer screening** Annual CT or MRI (preferred) Abdomen is indicated as an alternative to endoscopic ultrasound in **ANY** of the following scenarios: • Peutz-Jeghers syndrome (LKB1/STK11 mutations), starting at age 30-35 or 10 years earlier than youngest affected relative	April 14, 2024

	• Familial Atypical Multiple Melanoma and Mole syndrome (FAMMM; CDKN2A, p16 mutation), starting at age 40 or 10 years earlier than youngest affected relative • BRCA1, BRCA2, PALB2, ATM, EPCAM, TP53, or MLH1/MSH2/MSH6 (Lynch syndrome) gene mutation and at least one first- or second- degree relative* with pancreatic cancer, starting at age 50 or 10 years earlier than the youngest affected relative • Hereditary pancreatitis gene mutation (PRSS1 or SPINK1) with personal or family history of recurrent acute pancreatitis, starting at age 40 or 20 years after the initial onset of pancreatitis • Family history of pancreatic cancer, starting at age 50 or 10 years earlier than the youngest affected relative in **EITHER** of the following: ○ At least two first-degree relatives* ○ At least three first- and/or second-degree relatives* **Relative(s) with exocrine pancreatic cancer, on the same side of the family as the gene mutation or history of pancreatic cancer* **Explanation of change** Alignment with NCCN recommended parameters; changes are overall expansive, except for: ▪ Older start age (from 45 to 50) for certain genes (ATM, BRCA1, BRCA2, MLH1, MSH2, MSH6, EPCAM, PALB2, TP53) ▪ Family history alone (relative requirement)	
Breast Cancer		
Breast Cancer	**CT chest, CT abdomen and pelvis** Diagnostic Workup: Indicated for stage IIIA-IV or clinically suspected metastatic disease **Explanation of change:** Added diagnostic workup allowance when metastatic disease is clinically suspected at presentation. **MRI Breast** Surveillance: Indicated annually for a personal history of breast cancer after breast conserving therapy or unilateral mastectomy in ANY of the following scenarios: • Meets criteria for MRI breast screening • In patients with dense** breasts after breast conservation surgery and radiation therapy • Breast cancer diagnosis before age 50 **Explanation of change:** Addition/clarification of surveillance scenarios aligned with NCCN/ACR considerations **FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Radiation planning for treatment of locoregional recurrence • Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease • Evaluation of elevated LFTs or rising tumor markers when standard imaging has not clearly identified a site of recurrence or progression • Restaging/treatment response when bone is the only site of measurable disease in the chest, abdomen, and pelvis	April 14, 2024

	Explanation of change: Added allowance for RT planning locoregional recurrence (e.g. confirmation of regional nodal involvement). 18F-fluoroestradiol (18F-FES) PET/CT Suspected Cancer: Not indicated Diagnostic Workup: Not indicated Management: Not indicated Surveillance: Not indicated **Explanation of change:** Uncertain net benefit; low-level evidence, insufficient data on outcomes.	
Cervical Cancer		
Cervical Cancer	**FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease • Following radiation or chemoradiation when performed at least 12 weeks following completion of therapy • Signs or symptoms concerning for recurrent or metastatic disease **Explanation of change:** Update for follow-up of disease treated with either adjuvant RT or chemoradiation (NCCN alignment).	April 14, 2024
Hepatocellular and Biliary Tract Cancers		
Hepatocellular and Biliary Tract Cancers	**FDG-PET/CT** Diagnostic Workup and Diagnosis: Indicated when standard imaging cannot be performed or is nondiagnostic regarding the extent of disease **Management:** Indicated when standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease **Explanation of change:** Removal of routine preop PET/CT for biliary tract cancers (NCCN alignment) Added management allowance when standard imaging cannot be done or is nondiagnostic (NCCN "consider" for equivocal finding)	April 14, 2024
	Lung Cancer – Non-Small Cell	
Lung Cancer – Non-Small Cell	**FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Radiation planning for preoperative or definitive treatment • Evaluation following induction or neoadjuvant therapy, to determine eligibility for resection • Assessment of response to definitive chemoradiation when performed at least 12 weeks following therapy • Standard imaging cannot be performed, or is nondiagnostic for recurrent or progressive disease • Surveillance CT Chest demonstrates recurrence **Explanation of change:** Addition of management allowance when recurrence demonstrated by surveillance imaging (NCCN alignment)	April 14, 2024
Lung Cancer – Small Cell		

Lung Cancer – Small Cell	**FDG-PET/CT** Diagnostic Workup: Indicated prior to definitive therapy when standard imaging is nondiagnostic for extent of disease **Explanation of change:** Clarification of initial staging allowance (NCCN alignment)	April 14, 2024
Lymphoma – Non-Hodgkin and Leukemia		
Lymphoma – Non-Hodgkin and Leukemia	Lymphoma – Non-Hodgkin: Intermediate and high grade non-Hodgkin lymphoma **FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Radiation planning prior to definitive or consolidative treatment • Interim restaging following 2-4 cycles of treatment • Evaluation at completion of therapy • Evaluation of suspected recurrence or progression of disease based on standard imaging or objective signs/symptoms **Explanation of change:** NCCN alignment for interim restaging (allowed for DLBCL stage I-IV with or without bulky disease)	April 14, 2024
Melanoma		
Melanoma	**MRI Abdomen** Diagnostic Workup: See "Suspected or Known Metastases" Management: See "Suspected or Known Metastases" Surveillance: Indicated for uveal melanoma when liver ultrasound cannot be performed or nondiagnostic **Explanation of change:** Addition of surveillance option with MRI abdomen for liver metastases.	April 14, 2024
Prostate Cancer		
Prostate Cancer	**18F Fluciclovine PET/CT or 11C Choline PET/CT** **68GaProstate-specific membrane antigen (PSMA) PET/CT or 18F-DCFPyL (piflufolastat or Pylarify) PET/CT** Diagnostic Workup and Diagnosis: Indicated for unfavorable intermediate or high risk disease with equivocal or nondiagnostic conventional imaging,2 when confirmation may inform decisions about prostatectomy and/or radiation therapy Management: Indicated in **EITHER** of the following scenarios: • When **ALL** of the following criteria are met: ○ Original clinical stage T1-T3 and NX or N0 treated with prostatectomy and/or radiation therapy, with biochemically recurrent/persistent disease1 ○ Negative or nondiagnostic conventional imaging2 (within 60 days) if PSA ≥ 10 ng/ml ○ Patient is a candidate for curative intent salvage therapy3 ○ PET/CT has not been performed within the past 3 months • Evaluation of metastatic castrate-resistant disease for radioligand therapy when previously treated with taxane-based chemotherapy AND ANY of the following: ○ androgen-receptor pathway inhibitors ○ Abiaterone ○ Apalutamide	April 14, 2024

	○ Enzalutamide ○ Darolutamide **Explanation of change:** Addition of diagnostic workup/initial staging indication. Specification of androgen-receptor pathway inhibitor treatment in alignment with Carelon Radiation Oncology guidelines	
Sarcomas of Bone/Soft Tissue		
Sarcomas of Bone/Soft Tissue	**Bone Sarcoma, Soft Tissue Sarcoma** **FDG-PET/CT** Management: Indicated in **EITHER** of the following scenarios: • Following completion of neoadjuvant chemotherapy • Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease **Explanation of change:** Added allowance when standard imaging nondiagnostic or contraindicated (bone/soft tissue sarcoma).	April 14, 2024

Brain Imaging

The following updates will apply to the Carelon Clinical Appropriateness Guidelines for Radiology. 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
Neurodegenerative Conditions		
Movement disorders (Adult only)	**Movement disorders (Adult only)** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • For pre-procedural evaluation when MR-guided focused ultrasound (MRgFUS) is planned for essential tremor • For perioperative evaluation related to placement of a deep brain stimulator • For initial evaluation of the following movement disorders, to exclude an underlying structural lesion: ○ Hemifacial spasm ○ Huntington's disease ○ Multiple system atrophy ○ Parkinson's disease with atypical features ○ Progressive supranuclear palsy ○ Secondary dystonia ○ Other focal or lateralizing movement disorder, such as hemiballismus, athetosis, or chorea *Note: Imaging is generally not indicated for evaluation of typical Parkinson's disease or primary dystonia. Other than pre-procedural imaging for MRgFUS, imaging is generally not indicated for essential tremor.* **IMAGING STUDY** • CT brain • MRI brain (preferred) – for indications above other than essential tremor	April 14, 2024

	Explanation of change Added indication for CT head for assessment of skull density prior to MRgFUS for essential tremor	
Trauma		
Trauma	**Trauma** ***PEDIATRIC*** Advanced imaging is considered medically necessary in the diagnosis and management of head trauma in **EITHER** of the following scenarios: • Acute trauma when **ANY** of the following risk factors are present: ○ Altered mental status ○ Change in behavior ○ Vomiting ○ Loss of consciousness ○ History of high-risk motor vehicle accident or other mechanism of injury ○ Scalp hematoma when younger than age 2 years ○ Evidence of basilar skull fracture ○ Non-accidental injury • Non-acute trauma in **EITHER** of the following scenarios: ○ Focal neurological signs or symptoms that are new, progressive, or unexplained by CT performed for acute trauma ○ Progressive nonfocal neurologic signs or symptoms (including postconcussive syndrome) refractory to therapy ○ A follow-up study 3-6 weeks after head trauma in patients age 6 years or younger, when the neurologic exam is stable or inconclusive **Explanation of change:** Added a 3-6 week follow up study in patients age 6 or younger with stable or inconclusive exam, due to difficulty in accurately assessing for changes in neurologic status	April 14, 2024
Tumor or Neoplasm		
Acoustic neuroma	**Acoustic neuroma** *Also see indication for hearing loss.* *Also see Head and Neck Imaging guidelines.* Advanced imaging is considered medically necessary for management and surveillance of known acoustic neuroma in patients with neurofibromatosis type 2 or in **ANY** of the following scenarios: Management • Signs, symptoms or imaging findings suggestive of recurrence or progression Surveillance • Following conservative treatment (“watch and wait”) or incomplete resection (including proton beam therapy or stereotactic radiosurgery) annually for 5 years and then every 5 years thereafter • A follow up study following gross total resection within the first year after surgery, and follow-up studies at 2 years, 5 years, and 10 years after surgery **Explanation of change:** Added long-term follow-up intervals based on specialty society guidelines	April 14, 2024

Signs and Symptoms		
	Headache Advanced imaging is considered medically necessary to evaluate for an intracranial lesion as a secondary cause of headaches in **ANY** of the following scenarios: • Thunderclap or sentinel headache, sudden onset and severe (worst headache of life), reaching maximal intensity within minutes • Headache triggered by or occurring primarily in association with exertion or Valsalva including cough, exercise, or sexual activity • Positional or orthostatic headache • New onset of headache over age 50 • Change in headache pattern • Abnormal neurological exam • Unexplained and unexpected increase in frequency and/or severity of headaches **Explanation of change:** Modified language for clarity based on Operations feedback	April 14, 2024

Head and Neck Imaging

The following updates will apply to the Carelon Clinical Appropriateness Guidelines for Radiology. 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
Tumor/Soft Tissue Mass		
Acoustic neuroma	**Acoustic neuroma** Advanced imaging is considered medically necessary for management and surveillance of known acoustic neuroma in patients with neurofibromatosis type 2 or in **ANY** of the following scenarios: Management • Symptoms or imaging findings suggestive of recurrence or progression Surveillance • Following conservative treatment (“watch and wait”) or incomplete resection (including proton beam therapy or stereotactic radiosurgery) annually for 5 years and then every 5 years thereafter • A follow up study following gross total resection within the first year after surgery, and follow-up studies at 2 years, 5 years, and 10 years after surgery **Explanation of change:** Added long-term follow-up intervals based on specialty society guidelines	April 14, 2024
Signs and Symptoms		
Localized facial pain (including trigeminal neuralgia)	**Localized facial pain (including trigeminal neuralgia)** Advanced imaging is considered medically necessary for evaluation when localized facial pain is persistent and unexplained. **IMAGING STUDY** • CT orbit, sella, or posterior fossa and outer, middle, or inner ear	April 14, 2024

	• MRI orbit, face, and neck (soft tissue) **Explanation of change:** Added MRI orbit/face/neck for this indication based on ACR criteria; some facilities use MRI face rather than brain for this condition	

Chest Imaging
The following updates will apply to the Carelon Clinical Appropriateness Guidelines for Radiology. 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
Perioperative or periprocedural evaluation, not otherwise specified		
Navigational bronchoscopy planning for pulmonary mass or nodule	**Navigational bronchoscopy planning for pulmonary mass or nodule** Advanced imaging is considered medically necessary for use in navigational bronchoscopy when being done for **EITHER** of the following reasons: • Planning of a biopsy to be done using navigational bronchoscopy, when neither percutaneous biopsy nor traditional bronchoscopy can be performed. • Placement of fiducial markers for radiation therapy or localization for surgical resection of a pulmonary mass **IMAGING STUDY** • CT chest **Explanation of change:** Added indication for CT chest to be used for planning of biopsy or placement of fiducial markers using navigational bronchoscopy	April 14, 2024

Abdomen and Pelvis Imaging
The following updates will apply to the Carelon Clinical Appropriateness Guidelines for Radiology. 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
Hepatobiliary Indications		
Biliary tract dilatation or obstruction	**Biliary tract dilatation or obstruction** Advanced imaging is considered **medically necessary** for diagnosis and management in **ANY** of the following scenarios: • Unexplained biliary tract dilation • Biochemical evidence of biliary obstruction following nondiagnostic ultrasound • Annual evaluation of patients with Caroli disease or Caroli syndrome **Explanation of change:** Added indication for annual surveillance in Caroli disease/syndrome based on a 2022 guideline recommendation	April 14, 2024

Diffuse liver disease	**IMAGING STUDY** Multiparametric MRI (LiverMultiScan) as an alternative to MR elastography for diagnosis and management of advanced hepatic fibrosis/cirrhosis **Explanation of change:** Removed indication for LiverMultiScan in hemochromatosis as there is insufficient evidence that this provides an advantage over standard MRI for this condition	April 14, 2024
Osseous Indications		
Osteomyelitis	**Osteomyelitis** ***ADULT*** Advanced imaging is considered medically necessary following nondiagnostic radiographs. ***PEDIATRIC*** Advanced imaging is considered medically necessary for diagnosis and management **Explanation of change:** Added requirement for initial evaluation with radiographs in adult patients based on ACR appropriateness criteria	April 14, 2024
Septic arthritis	**Septic arthritis** ***ADULT*** Advanced imaging is considered medically necessary following nondiagnostic radiographs. ***PEDIATRIC*** Advanced imaging is considered medically necessary for diagnosis and management. **Explanation of change:** Added requirement for initial radiographs in adult patients based on ACR appropriateness criteria	April 14, 2024
Pancreatic Indications		
Pancreatic mass, indeterminate cystic (IPMN/IPMT)	**Pancreatic mass, indeterminate cystic (IPMN/IPMT)** ***ADULT*** Advanced imaging is considered medically necessary for diagnosis, management, and surveillance in surgical candidates when EUS/FNA has not been performed or is nondiagnostic in **ANY** of the following scenarios: • Initial evaluation of an indeterminate mass identified on ultrasound • Age 80 or greater at the time of diagnosis in **EITHER** of the following scenarios: ○ Every other year for up to 4 years if not increasing in size ○ Every 12 months if enlarging • Cysts less than 1.5 cm in a patient of age less than 80 at the time of diagnosis ○ Age less than 65 at diagnosis: every 12 months for up to 9 years from the time of initial diagnosis ○ Age 65 to 79 at diagnosis: every 24 months for up to 10 years from the time of initial diagnosis, or every 12 months if the lesion has worrisome features (enhancing nodules or peripheral calcification) or if the patient has high risk of pancreatic malignancy	April 14, 2024

	• Cysts 1.5 cm or greater in a patient of age less than 80 at the time of diagnosis Every 6-12 months for 2 years then yearly for up to 10 years **Explanation of change:** For enlarging lesions in patients age 80 or greater, increased surveillance frequency to annually and removed endpoint of 4 years.	
Miscellaneous Conditions		
Pelvic floor disorders	**Pelvic floor disorders** Advanced imaging is considered medically necessary for diagnosis and management in **ANY** of the following scenarios: • Functional disorder of the pelvic floor associated with urinary or bowel incontinence • Physical examination findings suspicious for pelvic organ prolapse • Chronic constipation, when anorectal manometry or balloon expulsion tests are nondiagnostic **IMAGING STUDY** • MRI pelvis (Dynamic MRI (MR defecography) technique is preferred[119, 120]) **Explanation of change:** Added indication for MRI (MR defecography preferred) in suspected pelvic organ prolapse based on ACR appropriateness criteria	April 14, 2024
Perioperative evaluation, not otherwise specified		
Transplant-related imaging	**Transplant-related imaging** Advanced imaging is considered medically necessary in the following scenarios: • For living donors, a single pre-transplant evaluation • For patients on the transplant waiting list for liver transplantation, annual surveillance • Single evaluation prior to lung, kidney, or hematopoietic stem cell transplantation • Evaluation of suspected post-transplant complications **Explanation of change:** Added indication for single CT abdomen or abdomen/pelvis prior to lung, kidney, or stem cell transplant to align with CT chest guidelines.	April 14, 2024

Radiation Oncology

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

Radiation Therapy
The following updates will apply to the Carelon Clinical Appropriateness Guidelines for Radiation Oncology. 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

Radiation Therapy (excludes Proton) IMRT for Colon Cancer		
IMRT for Colon Cancer	Intensity Modulated Radiation Therapy (IMRT) is appropriate for colon cancer when **EITHER** of the following conditions are met: • Adjuvant treatment of locally advanced adenocarcinoma of the cecum • To treat a previously irradiated field **Explanation of change:** New indication for adjuvant treatment of locally advanced adenocarcinoma of the cecum.	April 14, 2024
SBRT for Hepatocellular Carcinoma		
SBRT for Hepatocellular Carcinoma	Stereotactic Body Radiation Therapy (SBRT) is appropriate when **ANY** of the following conditions are met: • As palliative treatment for individuals with liver-related symptoms • As treatment of new or recurrent HCC unsuitable for surgery, embolization, or TACE, when these therapies have been done and have failed, or are contraindicated, when **BOTH** of the following conditions are met: ○ ≤ 5 HCC lesions with a sum of < 20 cm ○ Child-Pugh category A or Barcelona Clinic Liver Cancer Stage B or C disease ○ To treat a previously irradiated field **Explanation of change:** Modify eligibility criteria to match clinical trial RTOG 1112.	April 14, 2024
EBRT/IMRT for Prostate Cancer		
EBRT/IMRT for Prostate Cancer	**When the above criteria are met, the following fractionation applies:** The recommended EBRT/IMRT fractionation to treat localized prostate cancer when the pelvic lymph nodes will not be treated is either 60 Gy in 20 fractions or 70 Gy in 28 fractions. In men with significant baseline obstructive urinary symptoms, conventional fractionation of up to 39 fractions is considered medically necessary. Up to 39 fractions of EBRT/IMRT are considered medically necessary for localized or locally recurrent prostate cancer when the pelvic lymph nodes will be treated. Up to 36 fractions of EBRT/IMRT are considered medically necessary as adjuvant treatment to the prostate bed after prostatectomy. **Explanation of change:** Adjust for 2 Gy fractions. The total allowed dosage is the same with each fraction is a little larger (now 2 Gy) and lower number of fractions.	April 14, 2024

Proton Beam Therapy
No changes.

Therapeutic Radiopharmaceuticals
No changes.

Hydrogel Spacer for Prostate Radiotherapy
No changes

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.

MPC_033121-3Q-1-PO (rev 10/21)