MASSACHUSETTS

MEDICAL POLICY ANNOUNCEMENTS

Posted July 2025

This document announces new medical policy changes that take effect October 1, 2025.
Changes affect these specialties:

Cardiology
Behavioral Health
Endocrinology
Gastroenterology
Pulmonology Sleep Disorder Management
Pharmacy
Urology

Genetic Testing Guidelines. Effective September 20, 2025
Prenatal Screening using Cell-Free DNA
Carrier Screening in the Reproductive Setting
Genetic Testing for Inherited Conditions

Genetic Testing Guidelines. Effective November 15, 2025
Genetic Liquid Biopsy in the Management of Cancer and Cancer Surveillance
Somatic Tumor Testing

Radiology Guidelines. Effective November 15, 2025
Imaging of the Brain
Imaging of the Extremities
Imaging of the Spine
Imaging of the Heart
Vascular Imaging

Sleep Management Guidelines. Effective November 15, 2025
Polysomnography and Home Sleep Apnea Testing
Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing
Management of Obstructive Sleep Apnea using Auto-Titrating and Continuous Positive Airway Pressure Devices
Bi-Level Positive Airway Pressure Devices
Management of OSA using Oral Appliances
Miscellaneous Devices in the Management of OSA and Restless Legs Syndrome

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

Transcatheter Tricuspid Valve Repair or Replacement	036	**New medical policy** describing medically necessary and investigational indications.	October 1, 2025	Commercial	No action required. This procedure is performed in the inpatient setting.
Transcatheter Mitral Valve Repair or Replacement	692	**Policy revised.** New indication for transseptal valve-in-valve replacement added.	July 1, 2025	Commercial	No action required. This procedure is performed in the inpatient setting.
Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease	283	**Policy clarified.** CPT 82172 is considered investigational and not a covered service. 82172 Apolipoprotein, each	August 1, 2025	Commercial	No action required. This is not a covered service.

BEHAVIORAL HEALTH

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Applied Behavior Analysis (ABA)	091	**Policy revised** to include medically necessary indications for Down Syndrome.	October 1, 2025	Commercial	Prior authorization is required.

ENDOCRINOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid and Automated Insulin Delivery Systems	107	**Policy revised.** Automated Insulin Delivery Systems updated with new evidence, following FDA approval of the t:slim X2 insulin pump with Control-IQ+ technology for adults with type 2 diabetes. Medically necessary policy statement with criteria revised for	October 1, 2025	Commercial	Prior authorization is not required.

		individuals with type 2 diabetes. Artificial Pancreas Device Systems title changed to Automated Insulin Delivery Systems.			

GASTROENTEROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical and Surgical Management of Obesity including Anorexiants	379	**Policy revised** to include additional investigational endoscopic procedures.	October 1, 2025	Commercial	Prior authorization is required for surgical services.

PULMONOLOGY SLEEP DISORDER MANAGEMENT

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment Non-Covered Services List	400	**Policy revised.** HCPCS code K1027 **removed** from the noncovered list MP 400. Prior authorization is required through Carelon for K1027, effective October 1, 2025.	October 1, 2025	Commercial Medicare	Prior authorization is required through Carelon for K1027.
Sleep Disorder Management CPT and HCPCS Codes	970	**Policy revised.** The following codes were added: 0966T, 0964T, 0965T. These codes require prior authorization through Carelon effective October 1, 2025.	October 1, 2025	Commercial Medicare	Prior authorization is required through Carelon.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Gene Therapies for Hemophilia A or B	169	**Policy clarified** to remove Beqvez from the policy. Beqvez was discontinued by the manufacturer.	June 2, 2025	Commercial Medicare	No action required.
Non-Opioid Medications for Pain Management	040	**New pharmacy medical policy** containing prior authorization criteria for **Journavx**.	August 1, 2025	Commercial	Prior authorization is required.
Oncology Drugs (Oral and Subcutaneous)	409	**Policy revised.** Added new drugs **Itovebi** and **Lazcluze** to the policy.	August 1, 2025	Commercial	Prior authorization is required.
Medical Utilization Management (MED UM) & Pharmacy Prior Authorization Policy	033	**Policy revised.** Added Chronic Spontaneous Urticaria, Chronic Rhinosinusitis indication for **Dupixent**, added ATTR-CM indication for **Amvuttra**, added new drugs **Jubbonti, Wyost, Osenvelt, Stobclo**,and **Niktimvo**, and removed **Jetrea**, as product is discontinued.	August 1, 2025	Commercial	Prior authorization is required.
Glucagon-like Peptide (GLP-1) Receptor Agonists and Related Drugs for the Treatment of Type 2 Diabetes	056	**Policy revised.** Added indication for chronic kidney disease (CKD) to **Ozempic**.	August 1, 2025	Commercial	Prior authorization is required.
Drug Management & Retail Pharmacy Prior Authorization Policy	049	**Policy revised.** Updated **Attruby** criteria to align with other AATR-CM agents.	August 1, 2025	Commercial	Prior authorization is required.

Sublingual Immunotherapy with Allergen-specific Extracts (SLIT)	681	**Policy revised.** Updated age for **Odactra** indication to align with FDA label.	August 1, 2025	Commercial	Prior authorization is required.
Engineered T-Cell Therapy for Leukemia and Lymphoma (formerly *Chimeric Antigen Receptor Therapy for Leukemia and Lymphoma*)	066	**Policy revised.** Updated policy name to streamline CAR-T medical policy titles. Added new drug **Aucatzyl**.	August 1, 2025	Commercial	Prior authorization is required.
Engineered T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia Prior Authorization Request Form (formerly *CAR T-Cell Therapy Services for B-cell Acute Lymphoblastic Leukemia Prior Authorization Request Form*)	945	**Policy revised.** Updated Request Form title and added new section for **Aucatzyl**.	August 1, 2025	Commercial	Prior authorization is required.
Immune Modulating Drugs	004	**Policy revised.** Added Stelara biosimilars to the policy: **Selarsdi** and **Yesintek**.	August 2025	Commercial	Prior authorization is required.
Immune Modulating Drugs	004	**Policy revised.** Added criteria for Giant Cell Arteritis and Alopecia Areata. Added Stelara biosimilars to the policy as Non-Formulary: **Otulfi, Pyzchiva, Stegeyma,** and **Wezlana**. **Stelara** is also moving to non-formulary.	October 1, 2025	Commercial	Prior authorization is required.

UROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Nerve Graft in Association with Radical Prostatectomy	590	**Policy retired.** This procedure is generally performed in the inpatient setting. There is no specific code.	July 1, 2025	Commercial Medicare	No action required.
Tibial Nerve Stimulation	583	**Policy revised.** Transcutaneous tibial nerve stimulation (e.g., Vivally System) is considered **investigational** for individuals with bladder conditions of urinary incontinence and urinary urgency Title changed to "Tibial Nerve Stimulation."	October 1, 2025	Commercial Medicare	No action required.

Genetic Testing Guidelines

Legend	Text color	Indicates…
Guideline Change Summary	**Blue**	Change to guideline wording (*red for restrictive change)
	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

Policy Change Summary	Effective Date
Prenatal Screening using Cell-free DNA	
cfDNA screening **Not Medically Necessary:** The use of cfDNA screening is considered **not medically necessary** when screening for the following:	September 20, 2025

• Sex only (without family history of an X-linked disorder) • Single genes (e.g., CFTR, HBB, SMN1, RhD and/or other fetal red blood cell antigens) • 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 *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** **Clarified** cfDNA screening for fetal red blood cell antigens is considered not medically necessary	

Carrier Screening in the Reproductive Setting	
Cystic fibrosis and spinal muscular atrophy Standard screening for cystic fibrosis (CFTR testing) and spinal muscular atrophy (SMN1 testing) using accepted gene variant sets is considered **medically necessary** in the following scenarios: • All pregnant individuals • An individual considering reproduction **Explanation of change:** Clarification	September 20, 2025
Hemoglobinopathies Standard screening for hemoglobinopathies (HBA1/HBA2 and HBB testing) using hemoglobin electrophoresis or molecular genetic testing is considered **medically necessary** in the following scenarios IF no prior testing results (hemoglobin electrophoresis and/or HBA1/HBA2 and HBB gene analysis) are available for interpretation: • All pregnant individuals • An individual considering reproduction **Explanation of change:** Clarification	September 20, 2025
Expanded carrier screening **Multigene or single gene carrier screening** is considered **medically necessary** when ALL of the following criteria are met: • ONE or more of the following apply: ○ One or both individuals have ancestry (e.g., Ashkenazi Jewish, Finnish, French Canadian, among others) known to be at increased risk for certain conditions, other than cystic fibrosis, spinal muscular atrophy, and hemoglobinopathies ○ One or both individuals do not have access to a biological family history due to reasons such as adoption or use of a reproductive donor as documented in the member's medical record ○ The individual and their reproductive partner are known or suspected to be consanguineous as documented in the member's medical record • The condition(s) included in the screening test have at least a 1 in 100 carrier frequency* • The genetic disorder(s) being evaluated have gene-disease clinical validity AND pathogenic variants in the gene(s) are associated with significant morbidity and/or mortality in affected individuals	September 20, 2025

• The test has sufficiently high sensitivity and specificity to guide clinical decision making • Knowledge of the pathogenic variant(s) may be used for management of either the pregnancy or the potentially affected fetus or child, or for family planning **Note: Conditions on multigene panels can have carrier frequencies less than 1 in 100 for a consanguineous partnership.* **Explanation of change: Clarified** that carrier screening for a single gene condition can also be medically necessary when criteria are met	
Carrier testing based on family history Condition-specific carrier testing is considered **medically necessary** when **ANY** of the following criteria are met: • The individual has a previously affected child with the genetic condition being evaluated • Either partner has a first-, second-, or third-degree relative who is affected with or is a documented carrier of the genetic condition being evaluated • The reproductive partner of the individual being tested has a pathogenic variant or likely pathogenic in the gene associated with the condition being evaluated **Explanation of change:** Expanded medical necessity criteria to include having a relative who is a documented carrier of a genetic condition. Clarification	September 20, 2025
Fragile X syndrome carrier testing Fragile X premutation carrier testing is considered **medically necessary** in **EITHER** of the following scenarios: • Individuals assigned female sex at birth with a family history of fragile X-related disorders or intellectual disability suggestive of fragile X syndrome who are pregnant or considering pregnancy • Individuals assigned female sex at birth with unexplained ovarian insufficiency or failure, or an elevated follicle-stimulating hormone (FSH) level prior to age 40 **Explanation of change:** Clarifications	September 20, 2025

Genetic Testing for Inherited Conditions	
Cardiac conditions **Hereditary arrhythmia syndromes** Genetic testing for pathogenic variants associated with long QT syndrome, catecholamine polymorphic ventricular tachycardia (CPVT), or Brugada syndrome is considered **medically necessary** when A**NY** of the following are present: • The individual to be tested is symptomatic with supporting clinical and ECG features for long QT syndrome, or catecholamine polymorphic ventricular tachycardia (CPVT), or Brugada syndrome • The individual to be tested is presymptomatic with characteristic ECG features (at rest or with exercise) suggestive of an inherited cardiac arrhythmia syndrome AND the individual to be tested has a first-degree relative with ANY of the following: ○ Sudden cardiac death ○ Unexplained syncope ○ Unexplained cardiac arrest • There is a known familial pathogenic variant associated with long QT syndrome, catecholamine polymorphic ventricular tachycardia (CPVT), or Brugada syndrome in a first- or second-degree relative **AND**	September 20, 2025

• The genetic testing is focused on pathogenic variants relevant to the individual's suspected clinical diagnosis and known familial genetics **Explanation of change**: Clarification	
Primary mitochondrial diseases Genetic testing for primary mitochondrial disease is considered **medically necessary** when the following criteria are met (simplified modified Nijmegen criteria). An individual has an unexplained, progressive, multi-system disorder usually involving the central nervous system and/or neuromuscular system with findings, such as: • Brain MRI pathology associated with mitochondrial disease • Organic acid level pattern suggestive of a mitochondrial disease • Evidence of mitochondrial dysfunction in tissue **Order of testing when above criteria have been met** 1. Common mtDNA variant(s) testing or testing of nuclear gene(s) associated with the disease IF a specific primary mitochondrial disease is suspected (see Table 1) 2. Whole mtDNA genomic sequence and large-deletion analysis IF the individual's clinical presentation does **NOT** fit with a specific primary mitochondrial disorder (see Table 1) **OR** if the condition-specific test results are negative/uninformative 3. Targeted nuclear gene panel (<25 genes) testing IF whole mtDNA genomic sequence and large-deletion analysis does **NOT** yield a diagnosis *Note: Whole exome sequencing is considered medically necessary in some individuals. Please refer to the Whole Exome Sequencing and Whole Genome Sequencing guidelines.* **Explanation of change:** Developed new guideline section for primary mitochondrial diseases Expanded medically necessary testing for primary mitochondrial diseases to include mtDNA genomic sequence, large-deletion, and targeted nuclear mitochondrial gene panel analysis when clinical medical necessity criteria are met	September 20, 2025
Retinal disorders **Genetic** testing for pathogenic variants associated with inherited retinal disorders may be **medically necessary** when the **general requirements OR multi-gene panel criteria** listed above are met. Genetic testing for a known familial variant associated with an inherited retinal condition is medically necessary when BOTH of the following are met: • The individual to be tested has a first- or second-degree relative with a pathogenic or likely pathogenic variant associated with an inherited retinal condition • The testing is targeted to the gene of the known familial pathogenic or likely pathogenic variant **Explanation of change**: Specific call out for genetic testing for retinal disorders as medically necessary when the guideline general requirements or multi-gene panel criteria are met	September 20, 2025
Thrombophilia testing Thrombophilia genetic testing for common pathogenic variants associated with Factor V Leiden and/or the prothrombin (Factor II) gene G20210A is considered **medically**	September 20, 2025

necessary to inform anticoagulation decision-making when **ANY** of the following criteria are met: • An individual with an unprovoked or weakly provoked venous thromboembolism (VTE) at or before age 50 (weakly provoking factors include immobility or minor injury, illness, or infection) • An individual with recurrent VTE • An individual with VTE **AND EITHER** of the following: ○ Two or more family members with a history of VTE ○ One first-degree relative with VTE at or before age 40 • An individual with VTE involving the cerebral or splanchnic veins • An individual contemplating pregnancy who has a first-degree relative with VTE **AND** a confirmed hereditary thrombophilia • An individual with an unprovoked VTE is planning to stop anticoagulation and a positive test for thrombophilia would change this decision **Explanation of change**: **Clarified** what is meant by weakly provoking factors for venous thromboembolism with added examples Clarified that testing for FV Leiden and F2 testing is medically necessary when a positive FV Leiden or F2 test result would change plans for anticoagulation treatment in an individual with an unprovoked VTE	

Genetic Testing Guidelines

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Genetic Liquid Biopsy in the Management of Cancer and Cancer Surveillance (note revised title)	
Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer Genetic Liquid Biopsy in the Management of Cancer and Cancer Surveillance **Explanation of change:** Guideline renamed to encompass RNA based liquid biopsy tests	November 15, 2025
General Requirements The genomic testing must have established analytical and clinical validity and be performed in an appropriately certified laboratory. Repeated testing of the same individual for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study. Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios: • Repeated diagnostic testing of the same tumor site with no clinical change, treatment, or intervention since the previous study • Repeated diagnostic testing of the same individual and the same tumor by different providers over a short period of time **Explanation of change:** Clarification	November 15, 2025
Liquid Biopsy Testing **Definitions** **Genetic liquid biopsy** refers to the analysis of genetic material obtained from bodily fluids, primarily blood, to detect and monitor genetic changes associated with cancer. This technique focuses on identifying specific genetic pathogenic variants/likely pathogenic variants, alterations, or aberrations **in circulating tumor DNA (ctDNA) or other genetic components like RNA.** **Key applications of genetic liquid biopsy include:**	November 15, 2025

• **Pathogenic variant/likely pathogenic variant detection** – Identifying specific pathogenic variants/likely pathogenic variants in genes that are associated with certain types of cancer, which can guide targeted therapies • **Tumor profiling** – Understanding the genetic landscape of a tumor to identify potential treatment strategies and assess prognosis • **Monitoring treatment response** – Tracking changes in ctDNA levels over time to evaluate how well a cancer is responding to treatment • **Early detection and recurrence monitoring** – Detecting genetic changes that may indicate the presence of cancer at an early stage or the recurrence of a previously treated cancer **Explanation of change:** Include general information on genetic liquid biopsy testing	
General Criteria for Genetic Liquid Biopsy Testing If Cancer-site Specific Criteria (e.g., lung carcinoma, biliary tract carcinoma, breast carcinoma, prostate carcinoma) are described in this guideline, apply those criteria prior to use of the General Criteria for Genetic Liquid Biopsy Testing. The use of an FDA approved companion diagnostic test or an appropriately validated lab developed test (LDT) performed in a certified laboratory may be considered **medically necessary** when the following criteria are met. Liquid (ctDNA) based testing is considered **medically necessary** for individuals with invasive malignancy for whom the liquid biopsy test is necessary for treatment selection, and ALL the following criteria are met: • Specific cancer treatment is currently being considered which corresponds with an FDA companion diagnostic indication • 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 • The individual has not had prior testing for the targeted gene(s) of interest in the relevant clinical scenario • Other somatic tumor testing results or clinical criteria do not already provide support for the specific cancer therapy being considered that correspond to the FDA companion diagnostic indication and **ALL** the following criteria are met: ○ 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 ○ The genetic test is reasonably targeted in the scope of genetic testing applied ○ The genetic test has established clinical utility such that a positive or negative result will meaningfully impact the clinical management of the individual and will likely result in improvement in net health outcomes, AND ONE or more of these additional criteria must also be met: ▪ The genomic biomarker-linked therapies are approved by the US Food and Drug Administration (FDA) or recommended by NCCN as a Category 2A **for the individual's specific cancer scenario and such** therapies are being considered in the near term ▪ Treatment is being considered for which there are specific genomic biomarker-based contraindications or exclusions related to cancer treatment being considered in the near term aligned with the FDA label or NCCN 2A recommendations ▪ Treatment is being considered for which the member's health plan has a drug-specific policy requiring additional, appropriately focused	November 15, 2025

genetic biomarker testing otherwise not specified by the FDA label or NCCN 2A recommendation **Explanation of change:** Split liquid (ctDNA) based testing into **General Criteria** and **Cancer-site Specific Criteria** Lab developed tests added (expansive) Additional criteria added to meet medical necessity (restrictive)	

Cancer-site Specific Criteria	
Lung carcinoma **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 the following criteria are met: • 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 pathogenic variants/likely pathogenic variants (ESMO Scale for Clinical Actionability of Targets category 1A or 1B) to inform management at diagnosis or treatment progression on or after chemotherapy or immunotherapy **Explanation of change**: Clarification. ASCO and ESMO are comparable sets. ESMO Scale of Clinical Actionability for molecular Targets (ESCAT) status is easier to locate and updated more frequently.	November 15, 2025
Biliary tract carcinoma Individuals with locally advanced, recurrent, or metastatic biliary tract carcinoma Liquid (ctDNA) based testing is considered **medically necessary** for individuals with pathologically confirmed locally advanced, recurrent, or metastatic biliary tract carcinomas when **ALL** the following criteria are met: • 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 biliary tract cancer • The test is being used to provide genetic information related to the current set of actionable pathogenic variants/likely pathogenic variants (ESMO Scale for Clinical Actionability of Targets Category 1A or 1B) to inform management at diagnosis or treatment progression on or after chemotherapy or immunotherapy **Explanation of change:** New criteria added for biliary tract carcinoma (expansive)	November 15, 2025
Breast carcinoma **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** the following criteria are met: • The individual has ER-positive and HER2-negative metastatic breast cancer	November 15, 2025

• The individual is a candidate for drug treatment in the near term aligned with the FDA label or NCCN 2A recommendations • 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:** Removed restriction of individual needing to be an adult male or postmenopausal female (expansive) NCCN 2A recommendation added as positive criteria (expansive)	
Prostate carcinoma **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 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 PARP inhibitor with NCCN 2A recommendation) ○ FDA approved PD-1 inhibitor (pembrolizumab or other checkpoint inhibitor with NCCN 2A recommendation) • 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:** NCCN 2A recommendation added as positive criteria (expansive)	November 15, 2025

Individuals without malignancy for whom liquid biopsy is used for screening	
Individuals without malignancy for whom liquid biopsy is used for screening Liquid (ctDNA) based testing including multi-cancer early detection tests (MCED) 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. • The following **test examples are not medically necessary:** ○ Guardant Shield™ (Guardant Health) ○ Galleri® (GRAIL) **Explanation of change:** Test name examples added (clarifications)	November 15, 2025

ctDNA and Minimal Residual Disease (MRD)	
ctDNA and Minimal Residual Disease (MRD) 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. • The following test examples are **not medically necessary** ○ Guardant Response™ (Guardant Health) ○ Guardant Reveal™ (Guardant Health) ○ Signatera™ (Natera) **Explanation of change**: Test name examples added (clarifications)	November 15, 2025

Somatic Tumor Testing

General Requirements (apply to both Somatic Tumor Testing and Genetic Liquid Biopsy guidelines)	
The genomic testing must have established analytical and clinical validity and be performed in an appropriately certified laboratory. Repeated testing of the same individual for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study. Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios: • Repeated diagnostic testing of the same tumor site with no clinical change, treatment, or intervention since the previous study • Repeated diagnostic testing of the same individual and the same tumor by different providers over a short period of time **Explanation of change**: Clarification	November 15, 2025

Somatic Testing of Solid Tumors **General Criteria (previously Umbrella Criteria)**	
If Cancer-site Specific Criteria (e.g., breast cancer, colorectal cancer, prostate cancer, etc.) are described in this guideline, apply those criteria prior to use of the General Criteria. The use of an FDA approved companion diagnostic test or an appropriately validated lab developed test (LDT) performed in a certified laboratory may be considered **medically necessary** when the following criteria are met. **Explanation of change:** Clarifying information Lab developed tests added as medically necessary (expansive)	November 15, 2025
Somatic Genomic Testing (solid tumor biomarker testing) Somatic genomic testing is considered **medically necessary** in individuals with cancer when **ALL** the following criteria are met: • 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 • The genetic test is reasonably targeted in scope and has established clinical utility such that a positive or negative result will meaningfully impact the clinical management 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 the clinical utility is based on potential impact on clinical management based on genomic biomarker-linked therapies, one or more of these additional criteria must also be met: ○ The genomic biomarker-linked therapies are approved by the US Food and Drug Administration (FDA) or recommended by NCCN as a Category 2A for the individual's specific cancer scenario and such therapies are being considered in the near term ○ Treatment is being considered for which there are specific genomic biomarker-based contraindications or exclusions related to cancer treatment	November 15, 2025

being considered in the near term aligned with the FDA label or NCCN 2A recommendations ○ Treatment is being considered for which the member's health plan has a drug-specific policy requiring additional, appropriately focused genetic biomarker testing otherwise not specified by the FDA label or NCCN 2A recommendation **Explanation of change:** See last bullet: Allow genetic biomarker testing per member's health plan drug-specific policy requirements (expansive)	

Metastatic or Advanced Cancer (Tissue Agnostic Testing)	
Tissue-agnostic testing for patients with advanced solid tumors Multi-gene panel testing is considered **medically necessary** when **ALL** the following are true: • The individual has a metastatic or advanced solid tumor and adequate performance status for cancer treatment • There are no satisfactory tumor-specific standard therapies available • Tumor testing falls into one or more 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 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) ○ NTRK1/2/3 and RET fusion testing ○ BRAF V600E testing ○ FGFR1/2/3 fusions or pathogenic variants/likely pathogenic variants **Explanation of change:** Removal of restrictive criteria (expansive) Added FGFR biomarkers as medically necessary tumor testing (expansive)	November 15, 2025

Cancer-specific Criteria **Bladder Cancer (Urothelial Carcinoma, including the Upper Tract)**	
Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) 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 **Explanation of change**: IHC is out of scope for genetic testing	November 15, 2025
Targeted (i.e., 50 or fewer genes) tissue-based somatic tumor testing for FGFR pathogenic/likely pathogenic variants is considered medically necessary for individuals with urothelial tumors of the bladder or upper urinary tract when ALL 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) • The individual is a potential candidate for an FDA-approved (or NCCN 2A) targeted therapy prescribed on the basis of this testing	November 15, 2025

• The individual has not had prior FGFR testing in the locally advanced, recurrent, or metastatic setting **Explanation of change:** Clarifications NCCN 2A recommendation added to positive criteria (expansive) Removed restriction to a specific genetic biomarker (expansive)	

Brain Cancer (Malignant Glioma)	
Targeted (i.e., 50 or fewer genes) tissue-based somatic tumor testing is considered **medically necessary** for individuals with malignant gliomas of the brain when **ALL** 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) is considered **medically necessary** when **ALL** 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 *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 IHC is out of scope for genetic testing	November 15, 2025

Breast Cancer, localized; early adjuvant setting	
Gene expression profiling is considered **medically necessary** to guide adjuvant therapy* treatment-decision making for individuals with localized breast cancer using Oncotype DX, MammaPrint, EndoPredict, Prosigna, or the Breast Cancer Prognostic Gene Signature Assay when **ALL** the following criteria are met: • Surgery has been performed, and a full pathological evaluation of the specimen has been completed • Histology is invasive ductal, lobular, mixed, or metaplastic • Receptor status is estrogen receptor positive (ER+), progesterone receptor positive (PR+), or both; AND HER2-negative • Lymph node status is node-negative (pN0) or axillary lymph node micro-metastasis (pN1mi) less than or equal to 2 mm • Tumor features include **ANY** of the following: ○ Tumor size greater than 1.0 cm and less than or equal to 5.0 cm ○ Tumor size 0.6–1.0 cm and moderately (histologic grade 2) or poorly-differentiated (histologic grade 3) ○ Tumor size 0.6–1.0 cm and well-differentiated (histologic grade 1) with **EITHER** of the following: ▪ angiolymphatic invasion ▪ high nuclear grade (nuclear grade 3) • Chemotherapy is being considered by the individual and their provider	November 15, 2025

• No other breast cancer gene expression profiling assay has been conducted for this tumor (this includes testing on any metastatic foci or on other sites when the tumor is multifocal) [moved ***Note*** with others to follow all Breast Cancer criteria] Gene expression profiling is considered not **medically necessary** to guide adjuvant therapy treatment decision-making for individuals with ductal carcinoma in situ (DCIS) when DCIS is the sole breast cancer histology. **Explanation of change:** Clarifying. The Breast Cancer Index (BCI) was removed from early adjuvant setting. The BCI report provides information on use of EET at 5 years post-surgery. The report does not mention use of BCI test for purposes of adjuvant chemotherapy despite approval of the test for this indication by ASCO. NCCN mentions BCI in the context of EET only. This edit is done to provide clarity for reviewers who review BCI cases nearly exclusively for use of EET. A new section has been added allowing for the BCI test in the EET setting provided certain criteria are met.	

Breast Cancer, localized; extended adjuvant setting	
Gene expression profiling using the Breast Cancer Index (BCI) is considered **medically necessary** to assist with extended adjuvant therapy treatment-decision making for individuals with localized breast cancer when ALL the following criteria are met: • Receptor status is estrogen receptor positive (ER+), progesterone receptor positive (PR+), or both; AND HER2-negative • The individual is premenopausal at the time of the extended adjuvant decision-making • The individual has not been treated with ovarian suppression, an aromatase inhibitor, a CDK 4/6 inhibitor, or a PARP inhibitor **Explanation of change:** Added criteria for the Breast Cancer Index in extended adjuvant setting (expansive)	November 15, 2025

Breast Cancer, metastatic and/or locally advanced breast cancer**	
Targeted (i.e., 50 or fewer genes) tissue-based somatic tumor testing for pathogenic/likely pathogenic variants of PIK3CA, AKT1, PTEN, and ESR1 is considered **medically necessary** for postmenopausal females and adult males when **ALL** the following criteria are met: • The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for treatment per FDA label (or NCCN 2A) with alpelisib, capivasertib plus fulvestrant, or inavolisib with palbociclib and fulvestrant **AND/OR** the individual is a candidate for treatment per FDA label (or NCCN 2A) with elacestrant • The individual has not had prior tissue-based testing for the targeted gene(s) of interest in the metastatic setting ***Notes*** **Adjuvant therapy refers to treatments early in the trajectory of treatment for localized breast cancer (e.g., within 12 weeks of surgery) to reduce risk of breast cancer recurrence; this is distinct from extended-adjuvant therapy decision-making that takes places years after initiation of adjuvant treatment and involves a decision about the duration of treatment. [**moved** from early adjuvant]*	November 15, 2025

***Locally advanced breast cancer refers to AJCC stages IIIA, IIIB, or IIIC disease or stage IIB disease considered inoperable and requiring systemic therapy.* *Genetic Liquid Biopsy guideline criteria may apply; see Carelon Guidelines for Genetic Liquid Biopsy in the Management of Cancer and Cancer Surveillance. 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 genetic marker testing from 4 genes to 50 or fewer (expansive) NCCN 2A recommendation added to positive criteria (expansive) Clarifications	

Cholangiocarcinoma (Biliary Tract Cancers)	
Tissue-based somatic tumor testing for pathogenic/likely pathogenic variants in individuals with cholangiocarcinoma is considered **medically necessary** when **ALL** 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 the following genes: IDH1, FGFR, HER2/ERBB2, and BRAF • The individual is a potential candidate for targeted therapy that is FDA approved (or NCCN 2A), prescribed on the basis of the panel test results • The individual has not had prior somatic tumor testing for IDH1, FGFR, HER2/ERBB2, and BRAF in the metastatic setting **Explanation of change:** Clarifications Added another required genetic marker (restrictive) NCCN 2A recommendation added to positive criteria (expansive)	November 15, 2025

Colorectal Cancer	
Universal testing for all patients with newly diagnosed localized or metastatic colorectal cancer Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) is 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 **Explanation of change** IHC is out of scope for genetic testing	November 15, 2025
Localized colorectal cancer Targeted (i.e., 50 or fewer 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 ○ BRAF V600E ○ KRAS	November 15, 2025

○ MLH-1 promoter methylation (applicable when there is nuclear expression loss of MLH1 and PMS2 by IHC) **Explanation of change** Clarification IHC is out of scope for genetic testing	
Metastatic colorectal cancer Targeted (i.e., 50 or fewer 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** 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 pathogenic variants/likely pathogenic variants ○ POLD pathogenic variants/likely pathogenic variants ○ 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 **Explanation of change:** Clarifications	

Endometrial Carcinoma	
Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) 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 fewer 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** 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 gene testing (NGS) ○ P53 gene testing (NGS) • There has been no prior testing for these molecular aberrations **Explanation of change:** IHC is out of scope for genetic testing. Clarifications	November 15, 2025

Melanoma	
Prognostic testing in melanoma Gene expression profiling of indeterminate melanocytic skin lesions or of established cutaneous, mucosal, or uveal melanoma for prognostication is considered **not medically necessary**. *For multianalyte assays used for screening and diagnosis (often combined with algorithmic analyses), see the Carelon Guidelines for Predictive and Prognostic Polygenic Testing.*	November 15, 2025

Somatic tumor testing in advanced melanoma Tissue-based somatic tumor testing for **BRAF V600E** pathogenic variant by validated 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 **Additional testing in high-risk stage II-IV cutaneous melanoma or mucosal melanoma** Tissue-based somatic tumor testing (50 genes or fewer) for individuals with resectable or unresectable high-risk stage IIC, stage III or stage IV melanoma or mucosal melanoma is considered **medically necessary** when **ALL** the following criteria are met: • The individual has biopsy-proven malignant melanoma • Prior testing has not been performed • Testing includes **ANY** or **ALL** the following: [No criteria changes] **Additional somatic tumor testing in metastatic uveal melanoma** Testing of individuals with **metastatic uveal melanoma** for **HLA-A*0201** is considered **medically necessary** when **ALL** the following criteria are met: [No criteria changes] **Explanation of change:** Removed restriction requiring previous BRAF V600E testing (expansive) IHC is out of scope for genetic testing; Clarifications	

Non-Small Cell Lung Cancer, localized (stage IB-IIIA)	
Tissue-based somatic testing is considered **medically necessary** to identify EGFR and/or ALK pathogenic variant in individuals with localized NSCLC when **BOTH** of the following criteria are met: • Biopsy-proven, stage IB-IIIA NSCLC • Test results will determine candidacy for treatment with targeted agents used per FDA label (or NCCN 2A) **Explanation of change:** Testing for squamous cell histology is now allowed without the requirements of being age ≤50, non-smoker, or light former smoker (expansive) Added FDA label and NCCN 2A recommended treatments as allowed (expanded beyond two specific treatments)	November 15, 2025

Non-Small Cell Lung Cancer, advanced (previously metastatic)	
Tissue-based NGS panel testing is considered **medically necessary** to identify pathogenic/likely pathogenic variants in individuals with stage IIIB, IIIC, or IV (metastatic) NSCLC when **ALL** the following criteria are met: • Biopsy-proven NSCLC • The multi-gene NGS panel testing contains, at minimum*, testing of appropriate molecular aberrations (pathogenic variants/likely pathogenic variants, rearrangements, fusions, or amplifications) in **ALL** the following genes: EGFR, ALK, ROS1, BRAF, ERBB2 (HER2), KRAS, MET exon 14 skipping, NTRK, and RET • The multi-gene NGS panel contains NRG1 for fusion analysis **IF** use of zenocutuzumab-zbco therapy is being considered • The individual has not had prior tissue-based NGS testing in the metastatic setting, unless **BOTH** of the following are met:	November 15, 2025

○ There is evidence of disease progression while on EGFR-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.* **Explanation of change**: Testing for squamous cell histology is now allowed without the requirements of being age ≤50, non-smoker, or light former smoker (expansive) Added a marker for additional treatment option (expansive) Simplified criteria (expansive)	

Ovarian Cancer (Epithelial)	
Targeted (i.e., 50 or fewer genes) tissue-based somatic tumor testing to determine HRD status by testing for pathogenic/likely pathogenic variants of BRCA1, BRCA2 with concomitant evaluation for genomic instability is considered **medically necessary** when **ALL** the following criteria are met: • The individual has biopsy-proven locally advanced (stage III), metastatic (stage IV), or recurrent epithelial ovarian cancer • The individual has not had prior testing that establishes the presence of actionable germline or somatic pathogenic variants/likely pathogenic variants in BRCA1 or BRCA2 genes or eligibility for PARP-inhibitor treatment based on HRD status • The individual is a candidate for treatment with a PARP inhibitor per FDA label (or NCCN 2A) Germline testing for pathogenic/likely pathogenic variants is considered **medically necessary** for all individuals with epithelial ovarian carcinoma. *See Hereditary Cancer Testing guideline for further details.* **Explanation of change** Removed requirement for an FDA approved test (expansive) NCCN 2A recommendation added to positive criteria (expansive) Clarifications	November 15, 2025

Pancreatic Adenocarcinoma	
Germline testing for pathogenic/likely 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) 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 fewer genes) tissue-based somatic tumor testing is considered **medically necessary** when **ALL** 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, and NRG1 as applicable • The individual has not had prior tissue-based NGS testing in the locally advanced, metastatic, or recurrent setting **Explanation of change:** IHC is out of scope for genetic testing NRG1 added as an additional biomarker based on FDA approval (expansive) Specify prior tissue-based NGS testing Clarifications	November 15, 2025

Prostate Cancer, metastatic Current	
Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) 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/likely pathogenic variants in individuals with metastatic prostate cancer when **ALL** the following criteria are met: • The individual has biopsy-proven metastatic castration-sensitive adenocarcinoma of the prostate (mCSPC) with high burden of disease* or metastatic castration-resistant adenocarcinoma of the prostate (mCRPC) • The individual is a current or likely future candidate for **ONE** of the following therapies: ○ PARP inhibitor (olaparib, rucaparib, or another PARP inhibitor FDA approved or per NCCN 2A use in this setting) ○ PD-1 inhibitor (pembrolizumab or another checkpoint inhibitor FDA approved or per NCCN 2A 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, PALB2, RAD51B, RAD51C, RAD51D, and RAD54L • The individual has not had prior tissue-based NGS testing in the metastatic setting Germline testing for pathogenic/likely pathogenic variants is considered **medically necessary** for all individuals with metastatic prostate adenocarcinoma. *See Hereditary Cancer Testing guideline for further details.* **High burden of disease is defined per the STAMPEDE trial as the presence of visceral metastases or 4 or more bone metastases* **Explanation of change**: IHC is out of scope for genetic testing mCSPC and mCRPC specified as necessary types of prostate adenocarcinoma (restrictive) NCCN 2A recommendation added to positive criteria (expansive) Clarifications	November 15, 2025

Sarcoma (including soft tissue sarcoma, bone sarcoma, gastrointestinal stromal tumor, uterine sarcoma)	
Tissue-based somatic tumor testing for microsatellite instability (MSI by PCR) is considered **medically necessary** when **BOTH** of the following criteria are met: • The individual has biopsy or resection-proven sarcoma • The individual has not had prior MSI or dMMR testing Targeted (i.e., 50 or fewer genes) tissue-based somatic tumor testing by PCR or NGS* is considered **medically necessary** for individuals when **ANY** of the following criteria are met: • The individual has biopsy or resection proven sarcoma **or** a soft tissue neoplasm where molecular testing will establish the diagnosis • The individual is a potential candidate for an FDA-approved targeted therapy or ESMO Scale for Clinical Actionability of molecular Targets (ESCAT) level I gene alteration associated with drug therapy • The individual is a candidate for **ONE or more** of the following therapies:	November 15, 2025

○ FDA-approved kinase inhibitor (entrectinib, larotrectinib) approved for use with *NTRK1, NTRK2*, and *NTRK3* fusions without a known acquired resistance pathogenic variant/likely pathogenic variant ○ FDA-approved kinase inhibitor (selpercatinib) for adult and pediatric patients 2 years of age and older with locally advanced or metastatic solid tumors with a *RET* gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options ○ FDA-approved kinase inhibitor (avapritininb) with *PDGFRA (D842V)* pathogenic variants for GIST • The individual has not had prior testing for the same indication **SARCOMA SPECIFIC TESTING**: Whole blood **SYNOVIAL SARCOMA**: Whole blood DNA HLA-A locus sequencing for eligible alleles: HLA-A*02:01, HLA-A*02:02, HLA-A*02:03 or HLA-A*02:06 and their P-group alleles and exclusion alleles: HLA-A*02:05 and its P-group alleles in adults with unresectable or metastatic synovial sarcoma is considered **medically necessary** when **ALL** the following criteria are met: • The individual is a candidate for FDA-approved autologous T-cell immunotherapy (afamitresgene autoleucel) indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy **AND** • The tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices Table 1 lists genomic alterations recognized as either diagnostic, level 1 ESCAT changes associated with therapy (ESMO Scale for Clinical Actionability of molecular Targets), or Level 2A tests recommended in NCCN sarcoma guidelines. This list is a representative sample of some of the most common genomic alterations in sarcomas for which somatic molecular testing is medically necessary for diagnosis and/or treatment. Diagnostic targeted molecular or NGS panel testing for specific sarcoma types is listed below. The list is not exhaustive, and all listed genes are not required as to be included in an NGS test panel. [Table not shown here] **Explanation of change**: Expansive	

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** 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 neoplasm (FN) • The ITN is **≤** 4 cm • **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 **Somatic genetic testing of thyroid malignancy**	November 15, 2025

Tissue-based somatic tumor testing (50 genes or fewer) 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/likely pathogenic variants of BRAF V600E 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:** Removed restrictive ITN ultrasound criteria (expansive); Allow up to ITNs 4 cm in size (expansive). Clarifications	

Somatic Testing of Hematologic Malignancies **General Criteria (was Umbrella Criteria)**	
If hematologic malignancy specific criteria (e.g., acute myelogenous leukemia, chronic myeloid leukemia, multiple myeloma, etc.) are described in this guideline, apply those blood cancer criteria prior to use of the General Criteria. **Somatic Genomic Testing (blood cancer biomarker testing)** Somatic genomic testing is considered **medically necessary** in individuals with cancer when **ALL** the following criteria are met: • 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 • The genetic test is reasonably targeted in scope and has established clinical utility such that a positive or negative result will meaningfully impact the clinical management 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 the clinical utility is based on potential impact on clinical management based on genomic biomarker-linked therapies, one or more of these additional criteria must also be met: ○ The genomic biomarker-linked therapies are approved by the US Food and Drug Administration (FDA) or recommended by NCCN as a Category 2A for the individual's specific cancer scenario and such therapies are being considered in the near term ○ Treatment is being considered for which there are specific genomic biomarker-based contraindications or exclusions related to cancer treatment being considered in the near term aligned with the FDA label or NCCN 2A recommendations ○ Treatment is being considered for which the member's health plan has a drug-specific policy requiring additional, appropriately focused genetic biomarker testing otherwise not specified by the FDA label or NCCN 2A recommendation **Explanation of change**: NCCN 2A recommendation added to positive criteria; Allow for member's health plan drug-specific policy requirements to positive criteria (expansive)	November 15, 2025

Blood Cancer-specific Criteria **Acute Lymphoblastic Leukemia and Pediatric B-cell Precursor Lymphoblastic Lymphoma**

Initial Diagnosis 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) or pediatric B-cell precursor lymphoblastic lymphoma (BCP-LBL) 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 • A multi-gene panel contains genes that are identified with B-ALL, T-ALL or BCP-LBL, 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 **Measurable Residual Disease (MRD)** 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 pathogenic variant 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:** Added another cancer type (pediatric BCP-LBL) (expansive) Chromosomal testing is out of scope for genetic testing (clarifying)	November 15, 2025

Acute Myelogenous Leukemia	
Initial Diagnosis 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 **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 • A multi-gene panel contains genes that are identified with AML, such as FLT3 (including FLT3-ITD), 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 **Measurable Residual Disease (MRD)** 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** when used at appropriate 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, to measure minimal	November 15, 2025

residual disease (MRD) in individuals with AML involving **ONE** of the following disease molecular subtypes: • Acute promyelocytic leukemia (APL) • NPM1 • Core binding factor • Internal tandem duplication of FLT3 (FLT3-ITD) **Explanation of change**: Added FLT3-ITD as medically necessary (expansive) Chromosomal testing is out of scope for genetic testing (clarifying) Clarifications	

B-cell Lymphomas	
The use of focused multi-gene panel NGS testing (20 genes or fewer) on bone marrow specimens is **medically necessary** when **ALL** of the following criteria are met: • Individuals have high-grade B-cell lymphoma or diffuse large B-cell lymphoma (DLBCL) • Testing is for the purpose of establishing the diagnosis, to stratify risk, or to identify actionable therapeutic targets The use of multi-gene panel NGS testing on peripheral blood or bone marrow specimens is considered **not medically necessary** for individuals with B-cell lymphomas for the purpose of evaluating minimal residual disease (MRD). **Explanation of change:** New criteria for B-cell lymphomas (expansive)	November 15, 2025

Chronic Lymphocytic Leukemia	
Bone marrow tissue-based **OR** peripheral blood somatic genetic testing using a focused multi-gene panel NGS testing (20 genes or fewer) is **medically necessary** when **ALL** the following criteria are met: • Individuals have been diagnosed with chronic lymphocytic leukemia (CLL) • Testing is for the purpose of initial risk stratification and treatment selection • A multi-gene panel includes testing of TP53, SF3B1, NOTCH1, BIRC3, and ATM The use of multi-gene panel NGS testing on peripheral blood or bone marrow specimens is considered **not medically necessary** in members with CLL for initial workup or to measure minimal residual disease (MRD). **Explanation of change**: Criteria added for focused NGS panel for risk stratification (expansive)	November 15, 2025

Chronic Myeloid Leukemia	
Focused bone marrow tissue-based **OR** peripheral blood somatic genetic testing 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 pathogenic variant/likely pathogenic variant analysis is considered **medically necessary** in the monitoring of CML in the following circumstance: • Evaluation of individuals with CML to evaluate treated individuals who manifest suboptimal response to tyrosine kinase inhibitor therapy indicated by **ANY** of the following: ○ Lack of a partial hematologic or cytogenetic response at 3 months or greater after treatment onset ○ Less than a complete hematologic and cytogenetic response at 12 months ○ Disease progression to accelerated or blast phase	November 15, 2025

Measurable Residual Disease (MRD) testing 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 to 12, and every 3 months thereafter. **Explanation of change** Focused testing (clarifying) Chromosomal testing is out of scope for genetic testing (clarifying)	

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 • A multi-gene panel contains genes that are identified with MDS, such as ASXL1, DNMT3A, EZH2, NRAS, RUNX1, SF3B1, SETBP1, SRSF2, STAG2, TET2, TP53, U2AF1, ZRSR2, and UBA1 **Explanation of change:** Added genetic marker to examples (clarifying) Chromosomal testing is out of scope for genetic testing (clarifying)	November 15, 2025

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**. *For multianalyte assays used for prognostication (often combined with algorithmic analyses), see the Carelon Guidelines for Predictive and Prognostic Polygenic Testing.* **Measurable Residual Disease Testing** 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**: Chromosomal testing is out of scope for genetic testing (clarifying)	November 15, 2025

Advanced Imaging/Radiology Guidelines

Legend	Text color	Indicates…
Guideline Change Summary	**Blue**	Change to guideline wording (*red for restrictive change)
	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 Advanced Imaging/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

Imaging of the Brain	
Neurodegenerative Conditions **Neurocognitive disorders (Adult only)** *Includes mild cognitive impairment, dementia, and variants (e.g., vascular, Alzheimer's disease, frontotemporal degeneration spectrum, diffuse Lewy body).* Advanced imaging is considered medically necessary to direct management in **ANY** of the following scenarios: • Initial evaluation of documented cognitive abnormality when unexplained by clinical evaluation • Evaluation of rapidly progressive symptoms • In patients being treated with amyloid therapy (MRI brain only) **IMAGING STUDY** • CT brain • MRI brain (preferred) PET Brain is considered medically necessary to differentiate between frontotemporal dementia and Alzheimer's disease when substantial diagnostic uncertainty remains after **ALL** of the following: • Neuropsychological testing • Evaluation by a physician experienced in neurodegenerative disease • Structural imaging (CT or MRI) **IMAGING STUDY** • FDG PET or PET/CT • Amyloid Brain PET or PET/CT when amyloid therapy is being considered **Explanation of change:** Specification of MRI for amyloid therapy monitoring; expansion to remove intervals and include other amyloid therapies. Other formatting changes (no content change).	November 15, 2025
Trauma ***ADULT*** Advanced imaging is considered medically necessary in **EITHER** of the following scenarios: • Acute head trauma when **ANY** of the following risk factors are present:	November 15, 2025

○ Age 65 years or older ○ Retrograde amnesia ○ At least 2 episodes of emesis ○ Evidence of open, depressed, or basilar skull fracture ○ Focal neurologic findings ○ Glasgow coma scale less than 15 or altered mental status ○ High-risk mechanism of injury ○ Seizure ○ Bleeding diathesis/coagulopathy ○ Intracranial shunt • Subacute or chronic head trauma in **EITHER** of the following scenarios: ○ Cognitive or focal neurologic deficits ○ Nonfocal neurologic signs or symptoms (including post-concussive syndrome) refractory to therapy ***PEDIATRIC*** Advanced imaging is considered medically necessary in **EITHER** of the following scenarios: • Acute head 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 • Subacute or chronic head trauma in **ANY** of the following scenarios: ○ 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 ○ Cognitive or focal neurologic deficits ○ Nonfocal neurologic signs or symptoms (including post-concussive syndrome) refractory to therapy **Explanation of change:** Updated for non-acute trauma to align with ACR AUC recommendations, terminology clarifications	
Tumor or Neoplasm **Pituitary mass (including pituitary adenoma, incidentaloma)** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • Incidental pituitary lesion detected on CT or MRI, when at least 10 mm in size and not a simple cyst • Suspected pituitary adenoma when supported by signs or symptoms as well as laboratory findings • Management (including perioperative evaluation) of known adenoma • Surveillance of clinically stable adenoma in **EITHER** of the following: ○ Unresected adenoma ▪ Macroadenoma (size greater than 10 mm) ▪ Microadenoma (size 10 mm or less): Annual surveillance imaging ○ Resected adenoma ▪ At least 3 months following resection **Explanation of change** Combined pituitary tumor sections; incidentaloma size threshold aligned with cited ACR white paper.	November 15, 2025

Seizure disorder and epilepsy ***ADULT*** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • Initial evaluation of new or changing seizure, to rule out a structural brain lesion • Seizures increasing in frequency or severity despite optimal medical management • Prior to discontinuation of anticonvulsant therapy in patients who have not been previously imaged • Epilepsy refractory to optimal medical management in surgical candidates ***PEDIATRIC*** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • Neonatal/infantile seizure (age 2 years or younger) when **EITHER** of the following is present: ○ Initial evaluation of seizure not associated with fever ○ Periodic follow up at 6-month intervals up to 30 months, if initial imaging study is nondiagnostic • Childhood/adolescent seizure (over age 2) when **ANY** of the following is present: ○ Focal neurologic findings at the time of the seizure ○ Persistent neurologic deficit in the postictal period ○ Idiopathic generalized epilepsy with atypical clinical course ○ Partial or absence seizures ○ Nondiagnostic EEG ○ Seizures increasing in frequency or severity despite optimal medical management ○ Prior to discontinuation of anticonvulsant therapy in patients who have not been previously imaged ○ Epilepsy refractory to optimal medical management in surgical candidates • Complex febrile seizure (age 6 months to 5 years) when **EITHER** of the following is present: ○ More than one seizure during a febrile period ○ Seizure lasting longer than 15 minutes *Note: Imaging is not generally indicated for simple febrile seizures.* **IMAGING STUDY** • CT brain • MRI brain • Functional MRI (fMRI) in epilepsy refractory to optimal medical management in surgical candidates when done as a replacement for a Wada test or direct electrical stimulation mapping • PET brain imaging in epilepsy refractory to optimal medical management in surgical candidates **Explanation of change:** Added allowance for absence seizure, other clarifications aligned with operational intent	November 15, 2025
Procedural Imaging (Previously Perioperative/Periprocedural Imaging) **Magnetoencephalography and magnetic source imaging** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • Preoperative seizure localization for intractable epilepsy, when MRI is nondiagnostic • Preoperative mapping of eloquent cortex **IMAGING STUDY**	November 15, 2025

• Magnetoencephalography (MEG) or magnetic source imaging (MSI) **Explanation of change:** New guideline content (codes already managed for Elevance plans)	
Signs and Symptoms **Dizziness or vertigo** *Also see Head and Neck Imaging guidelines* Advanced imaging is considered **medically necessary** for dizziness associated with **ANY** of the following: • Abnormal neurologic exam, audiogram or vestibular function testing suggestive of an intracranial or vestibulocochlear mass lesion • Unilateral hearing loss or tinnitus • Tullio's phenomenon (noise-induced dizziness) **Explanation of change** Specification of objective findings aligned with ACR AUC; including current Hearing loss/Tinnitus allowances.	November 15, 2025
Headache Advanced imaging is considered **medically necessary** to evaluate headache not previously imaged by MRI in **ANY** of the following scenarios: • Thunderclap or sentinel headache (sudden onset and severe, or 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 headache onset after age 50 • Change in headache pattern • Abnormal neurological exam • Unexplained and unexpected increase in frequency and/or severity of headaches • Trigeminal autonomic cephalgia (TAC), including cluster headaches • Comorbid conditions that increase the likelihood of an intracranial lesion, including malignancy, immunosuppression, sarcoidosis, neurocutaneous disorders (phakomatoses), or pregnancy *Note: For headache related to trauma, infection, aneurysm, venous sinus thrombosis or other specific diagnoses, please refer to those indications in the Brain Imaging or Vascular Imaging guidelines* *For typical migraine or tension-type headache, without red flags and without a change in pattern, advanced imaging is not indicated.* **Explanation of change** Specification of prior imaging to allow MRI evaluation, additional clarifications (no operational change)	November 15, 2025

Imaging of the Extremities	
Infection **Septic arthritis**	November 15, 2025

Advanced imaging is considered **medically necessary** for diagnosis and management when radiograph, ultrasound, or arthrocentesis is nondiagnostic or not sufficient to guide treatment. IMAGING STUDY • MRI upper or lower extremity (joint) **Explanation of change:** Removal of non-joint modality for joint indication	
Inflammatory Conditions **Myositis** Advanced imaging is considered medically necessary in **EITHER** of the following scenarios: • Clinically suspected myositis, for imaging confirmation or localization for biopsy • Monitor response to therapy **Explanation of change:** Clarification/expansion to allow imaging confirmation	November 15, 2025
Trauma **Fracture** Advanced imaging is considered **medically necessary** in **ANY** of the following scenarios: • Detection of occult fracture following nondiagnostic radiographs at high-risk/weight bearing sites: ○ Upper extremity: ▪ Scaphoid ▪ Lunate ○ Lower extremity: ▪ Femoral neck, proximal femur ▪ Tibia (anterior tibial cortex; tibial plateau; medial malleolus) ▪ Patella ▪ Talus ▪ Navicular ▪ Metatarsal base (second and fifth digits) ▪ Great toe sesamoid ▪ Calcaneus (in individuals when imaging will direct the timing of return to vigorous athletic activity) • Following radiographs demonstrating supracondylar, intra-articular, or Salter-Harris (growth plate) fractures (including tibial plateau fracture) • To assess fracture healing for delayed union or nonunion when radiographs are nondiagnostic **IMAGING STUDY** • MRI upper extremity (joint or non-joint); MRI lower extremity • CT upper or lower extremity for evaluation of supracondylar, intra-articular, or Salter-Harris fractures • CT upper or lower extremity for detection of occult fracture when MRI cannot be performed • CT upper extremity (joint or non-joint) for delayed union or nonunion of the scaphoid as an alternative to MRI **Explanation of change:** Addition of high-risk site (medial malleolus) Clarification for intra-articular fracture (no operational change)	November 15, 2025

Tumor/Neoplasm **Soft tissue mass – not otherwise specified** Advanced imaging is considered **medically necessary** in **ANY** of the following scenarios: • Superficial or palpable non-popliteal mass, following nondiagnostic radiograph or ultrasound • Superficial or palpable popliteal (posterior knee) mass, following nondiagnostic radiographs and ultrasound • Soft tissue evaluation when prominent or unexplained calcifications are seen on radiograph **Explanation of change:** Removal of unsupported content; other clarification (no operational change)	November 15, 2025
Conditions of the Upper Extremity (previously Ligament and Tendon Derangement of the Upper Extremity) **Labral tear – shoulder** Advanced imaging is considered **medically necessary** for suspected labral tear in ANY of the following scenarios: • History of shoulder dislocation or recurrent subluxation, with persistent pain and/or instability • Acute trauma with either evidence of suprascapular nerve entrapment or radiographic suspicion of a bony Bankart lesion (anteroinferior glenoid fracture) • Pain with at least one physical exam finding of SLAP tear, nondiagnostic radiograph and failure of at least 6 weeks of conservative management **Explanation of change:** Expanded/simplified criteria aligned with Carelon MSK guidelines. Added XR per ACR AUC for chronic shoulder pain, alignment with joint imaging thresholds.	November 15, 2025
Ligament and tendon injuries – wrist Advanced imaging is considered **medically necessary** following nondiagnostic radiographs in **ANY** of the following scenarios: • Suspected scapholunate ligament tear • Acute triangular fibrocartilage complex (TFCC) tear • Chronic TFCC tear with failure of at least 6 weeks conservative management **IMAGING STUDY** • MRI upper extremity (joint) • CT when MRI cannot be performed or is nondiagnostic **Explanation of change:** Removal of operationally vague scenario now addressed under UE Pain NOS; section combined with TFCC tear (no content change)	November 15, 2025
Conditions of the Lower Extremity (previously Ligament and Tendon Derangement of the Lower Extremity) **Labral tear and femoral acetabular impingement – hip** Advanced imaging is considered **medically necessary** in **EITHER** of the following scenarios: • Suspected labral tear with **ALL** of the following: • Hip pain, **OR** positive impingement on exam • Nondiagnostic radiograph (without advanced osteoarthritis, or normal) • Failure of at least 6 weeks of conservative management	November 15, 2025

Explanation of change: Simplification of pain description, XR requirement aligned with MSK guideline	
Meniscal tear/injury Advanced imaging is considered **medically necessary** following nondiagnostic radiographs in **EITHER** of the following scenarios: • Knee pain with symptoms of locking, catching, or instability **AND** at least **TWO** of the following physical exam findings of meniscal tear: • Joint swelling or effusion • Positive McMurray or Apley test • Joint line tenderness • Reduced range of motion • Knee pain with at least **ONE** physical exam finding of meniscal tear and failure of at least 6 weeks of conservative management **Explanation of change:** Alignment with Carelon MSK Joint surgery guideline thresholds	November 15, 2025
Pain, unspecified **Lower extremity pain, not otherwise specified** *Applies when focused history and physical exam have not provided a likely diagnosis.* Advanced imaging is considered **medically necessary** for persistent pain when **BOTH** of the following criteria are met: • Radiographs are nondiagnostic (and without severe osteoarthritis) • Failure of at least 6 weeks of conservative management **IMAGING STUDY** • MRI lower extremity • CT lower extremity when MRI cannot be performed or is nondiagnostic **Upper extremity pain, not otherwise specified** *Applies when focused history and physical exam have not provided a likely diagnosis.* Advanced imaging is considered **medically necessary** for persistent pain when **BOTH** of the following criteria are met: • Radiographs are nondiagnostic (and without severe osteoarthritis) • Failure of at least 6 weeks of conservative management **Explanation of change** Removal of site-specific exclusions for Pain NOS with aligned thresholds for conservative management; updated OA grading	November 15, 2025

Imaging of the Spine	
Infectious and Inflammatory Conditions **Axial spondyloarthropathy** *Includes ankylosing spondylitis, reactive arthritis, psoriatic arthritis, spondyloarthropathy associated with inflammatory bowel disease, and juvenile-onset spondyloarthritis* Advanced imaging of the spine is considered medically necessary in **ANY** of the following scenarios: • Diagnosis of spondyloarthritis (SpA) when **ALL** of the following are present: ○ Inflammatory back pain* for at least 3 months	November 15, 2025

○ Radiographs and MRI of the sacroiliac joints are negative or equivocal for sacroiliitis • Management for **EITHER** of the following: ○ On biologic therapy for treatment spondyloarthritis (nrSpA), with unclear disease activity after full clinical and laboratory evaluation, when progression on MRI will lead to an alteration of management ○ Suspected fracture in setting of known spinal ankylosis **IMAGING STUDY** • CT cervical, thoracic, or lumbar spine • MRI cervical, thoracic, or lumbar spine (preferred) **Inflammatory back pain characteristically includes the following features: insidious onset, improvement with exercise, no improvement with rest, occurring at night, and age of onset <40 years of age.* **Explanation of change:** Expanded and simplified allowances aligned with cited diagnostic thresholds	
Miscellaneous Conditions of the Spine **Vertebral compression fracture** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • New symptomatic vertebral compression fracture by radiograph, when vertebroplasty or kyphoplasty is being considered • Vertebral compression fracture with history of malignancy • Previously treated compression fracture(s) with new back pain • Suspected fracture in setting of known spinal ankylosis **Explanation of change:** Changes in alignment with ACR AUC recommendations	November 15, 2025
Pain, Radiculopathy and Spinal stenosis (Previously Pain Indications) **Neck pain or cervical radiculopathy** Advanced imaging is considered **medically necessary** in **EITHER** of the following scenarios: • Neurologic exam findings suggesting cervical nerve root or cord compression that has not previously been imaged, or is new since last imaging was performed • Pain or radiculopathy following at least 6 weeks of conservative management **Mid-back pain or thoracic radiculopathy** Advanced imaging is considered **medically necessary** in **EITHER** of the following scenarios: • Neurologic exam findings suggesting thoracic nerve root or cord compression that has not previously been imaged or is new since last imaging was performed • Pain or radiculopathy following at least 6 weeks of conservative management **Low back pain or lumbar radiculopathy** ***ADULT*** Advanced imaging is considered **medically necessary** in **EITHER** of the following scenarios: • Neurologic exam findings suggesting lumbar nerve root or cord compression that has not previously been imaged or is new since last imaging was performed • Pain or radiculopathy following at least 6 weeks of conservative management ***PEDIATRIC***	November 15, 2025

Advanced imaging is considered **medically necessary** in **ANY** of the following scenarios: • Pain with nondiagnostic radiographs and **ANY** of the following characteristics: ○ Constant ○ Occurs at night ○ Radicular ○ Duration greater than 4 weeks and not responsive to conservative management • Neurologic exam findings suggesting lumbar nerve root or cord compression that has not previously been imaged or is new since last imaging was performed **Explanation of change** Added specification for new neurologic findings Removed intervention candidacy requirement Removed cervical x-ray requirements aligned with ACR AUC. Condensed Radiculopathy and Adult/Peds (no content change)	
Spinal stenosis and spondylolisthesis Advanced imaging is considered **medically necessary** in **ANY** of the following scenarios: • Acute onset of neurogenic claudication in patients who are not candidates for conservative management due to intractable pain • Chronic neurogenic claudication that has not responded to at least 6 weeks of conservative management • Spondylolisthesis, with evidence of instability on lumbar spine radiographs **Explanation of change:** Removed intervention candidacy requirement. Title clarification; removed scenario addressed in other sections (not content change)	November 15, 2025

Imaging of the Heart	
Coronary CT Angiography/ MRI Cardiac/ PET Perfusion Imaging/ Myocardial Perfusion Imaging/ Stress Echocardiography **Imaging Considerations** • …. • For purposes of this guideline, a patient is considered to have had preceding evaluation of coronary artery disease if any of the following have been performed: Stress testing with adjunctive imaging (nuclear, echo, PET, MRI) or coronary angiography (CCTA or invasive). **Explanation of change:** In several guidelines the appropriateness of imaging is based on whether the patient has had a preceding evaluation for CAD. Reviewers had requested that the term "preceding evaluation for CAD" be defined	November 15, 2025
Established or suspected CAD **Patients with abnormal or inconclusive exercise treadmill test (performed without imaging) who have not undergone evaluation for CAD since the treadmill test** • Abnormal findings on an exercise treadmill test include chest pain, ST segment change, abnormal blood pressure response, or complex ventricular arrhythmias • Provided that criteria for positivity (as outlined above) are not present, an exercise EKG test is deemed to be inconclusive when target heart rate was not reached or when the protocol could not be completed for other reasons (e.g. non-cardiac symptoms, inability to walk on a treadmill, other safety concerns). **Explanation of change** Addition of inconclusive exercise treadmill test as an indication for additional CAD testing	November 15, 2025
Established or suspected CAD **Preoperative cardiac evaluation of patients undergoing non-emergency non-cardiac surgery** *Note: It is assumed that those who require emergency surgery will undergo inpatient preoperative evaluation.* Stress testing with adjunctive imaging or CCTA/Cardiac MRI/Perfusion PET/MPI/SE is considered medically necessary when **ALL** of the following (A-C) apply A. At least two (2) of the following • Age ≥ 75 years • History of heart disease (myocardial infarction [MI], PCI, cardiac surgery, heart failure, atrial fibrillation, or moderate/severe valvular disease confirmed by echocardiography) • Angina or dyspnea • Hemoglobin <12 g/dl • The proposed surgery is vascular B. Poor or unknown functional capacity C. The proposed surgery is an elevated risk procedure* *All surgical procedures **EXCEPT** those listed below are considered elevated risk: • ophthalmologic • dental • endoscopic (including arthroscopic) • endocrine	November 15, 2025

• breast • obstetric /gynecological • dermatological Prior to considering elective surgery, patients with active cardiac conditions such as unstable coronary syndromes (unstable angina), decompensated heart failure (NYHA class IV, worsening or new onset heart failure), significant arrhythmias (third degree AV block Mobitz II AV block, uncontrolled supraventricular arrhythmia, symptomatic ventricular arrhythmias, ventricular tachycardia), symptomatic bradycardia or severe stenotic valvular lesions should be evaluated and managed per ACC/AHA guidelines. **That evaluation may include CCTA/Cardiac MRI/Perfusion PET/MPI/SE**. • **Low-risk surgery** (endoscopic procedures, superficial procedures, cataract surgery, breast surgery, ambulatory surgery) **Explanation of change** Include preoperative stress testing in alignment with 2024 AHA/ACC/ACS/ASNC/HRS/SCA/SCCT/SCMR/SVM guideline for perioperative cardiovascular management for noncardiac surgery: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. JACC. 2024;84(19):1869–1969.	

Vascular Imaging	
Procedure-related Imaging **Vascular evaluation prior to transcatheter aortic valve implantation/replacement (TAVI/TAVR) or cardiac surgery** **Explanation of change** Cardiac surgery added to Procedure-related imaging (allows CT or CTA chest).	November 15, 2025
Brain, Head and Neck **Stenosis or occlusion, extracranial carotid arteries** *See separate indication for acute stroke or transient ischemic attack.* Vascular imaging is considered **medically necessary** in patients who are candidates for carotid revascularization in **ANY** of the following scenarios: • Screening ○ Starting 5 years post-neck irradiation and every 3 years thereafter • Diagnosis of suspected carotid stenosis ○ Hollenhorst plaques (cholesterol emboli) or retinal neovascularity on retinal examination • Management of known carotid stenosis ○ Worsening neurologic symptoms or signs attributable to the anterior circulation • Surveillance of established carotid disease in asymptomatic persons with no prior revascularization: ○ Moderate (50%-69%) stenosis: every 12 months ○ Severe (70% or greater) stenosis: every 6 months • Post-revascularization: baseline evaluation, then every 6 months for 2 years, then annually **Explanation of change** Combined post-revascularization imaging and updated alignment with SVS guidelines. Cardiac surgery item moved to Procedure related imaging.	November 15, 2025

Stroke or transient ischemic attack (TIA), intracranial evaluation *Also see Brain Imaging guidelines.* Vascular imaging is considered **medically necessary** in **ANY** of the following scenarios, when no prior intracranial imaging since the stroke/TIA event: • Acute or subacute stroke/TIA (within 30 days of signs or symptoms other than syncope) • Chronic (30 days or more) stroke/TIA with signs or symptoms other than syncope attributable to the posterior circulation **Explanation of change:** Simplification for acute/subacute stroke/TIA by timing, specification for same-episode imaging	November 15, 2025
Stroke or transient ischemic attack (TIA), extracranial evaluation Vascular imaging is considered **medically necessary** in **ANY** of the following scenarios, when no carotid imaging since the stroke/TIA event: • Acute or subacute stroke/TIA (within 30 days of signs or symptoms other than syncope) • Chronic (30 days or more) stroke/TIA in **EITHER** of the following scenarios: ○ Signs or symptoms attributable to the anterior (carotid) circulation, in patients who are candidates for carotid revascularization ○ Signs or symptoms other than syncope attributable to the posterior circulation **IMAGING STUDY** • Duplex arterial ultrasound (any indication) • CTA or MRA neck for acute/subacute stroke/TIA and chronic posterior circulation stroke/TIA • CTA or MRA neck for chronic anterior circulation stroke/TIA when duplex arterial ultrasound cannot be performed or is nondiagnostic **Explanation of change:** Simplification for acute/subacute stroke/TIA by timing, specification for same-episode imaging	November 15, 2025
Venous thrombosis or compression, intracranial *Includes dural venous sinus thrombosis, venous sinus thrombosis, and cerebral vein thrombosis* Advanced imaging is considered **medically necessary** in **ANY** of the following: • Suspected venous sinus thrombosis in setting of headache, visual changes, eye pain or other neurologic symptoms, with **ANY** of the following: ○ Papilledema, cranial nerve palsy, or focal neurologic deficit on exam ○ Risk factor for venous thrombosis ○ Elevated D-dimer ○ Suspicious or nondiagnostic CT head or MRI brain • History of venous sinus thrombosis, with current signs or symptoms of recurrent thrombosis • Follow-up of known venous sinus thrombosis • To exclude venous compression by an adjacent intracranial mass **IMAGING STUDY** • CTA or MRA head • CT brain or MRI Brain **Explanation of change:** Simplification of content by common presentation, allowance of CT/MRI in lieu of CTA/MRA, other clarifications.	November 15, 2025

Chest **Acute aortic syndrome** *Includes aortic dissection, rupture, intramural hematoma, penetrating ulcer, and pseudoaneurysm* Advanced imaging is considered **medically necessary** in **ANY** of the following scenarios: • Initial diagnosis of suspected disease • Management of known disease • Annual surveillance of clinically stable disease **IMAGING STUDY** • CT or CTA chest • MRA chest **Explanation of change:** Added CT allowance (contrast CT may be sufficient for eval)	November 15, 2025
Upper Extremity Physiologic testing for peripheral arterial disease Physiologic testing is considered **medically necessary** for diagnosis and management in **ANY** of the following scenarios: • New or worsening signs or symptoms (**ANY** of the following): ○ Claudication ○ Unilateral cold painful hand (including resting ischemic pain) ○ Finger discoloration or ulcer ○ Non healing arm ulcers or gangrene ○ Absent pulses of the arm or hand associated with infection • Arterial entrapment syndrome or positional arterial obstruction • Arm or hand trauma and a suspicion of vascular injury • Preoperative evaluation in EITHER of the following: ○ Evaluation of native arteries prior to arteriovenous fistula or graft for dialysis access ○ Prior to planned harvest of the arterial harvesting (e.g., for CABG) • Suspected complication of upper extremity arterial access (including suspected arterial steal) • Post procedure baseline and initial 6 month follow up after revascularization with a vein bypass graft • Annual surveillance starting 1 year after revascularization with a vein or prosthetic bypass graft **Explanation of change:** Alignment of preop indications with Duplex US criteria; other clarifications	November 15, 2025
Lower Extremity **Physiologic testing for peripheral arterial disease** Physiologic testing is considered **medically necessary** for diagnosis and management in **ANY** of the following scenarios: • New or worsening signs or symptoms (**ANY** of the following): ○ Claudication ○ Resting limb pain with diminished or absent pulses ○ Non healing ulcers or gangrene ○ Absent pulses of the leg or foot	November 15, 2025

• Acute limb ischemia • Baseline in newly diagnosed peripheral arterial disease (ABI) or prior to revascularization (segmental pressure measurements) • Post-revascularization: ○ Post procedure baseline evaluation ○ After surgical revascularization: At 3-month intervals within the first 2 years, and annually thereafter ○ After endovascular revascularization*: At 4-month intervals within the first year, and annually thereafter **IMAGING STUDY** Limited, complete, or noninvasive physiologic studies *Endovascular revascularization may include angioplasty, thrombectomy, atherectomy, or stent placement **Explanation of change:** Alignment of post-revascularization indications with Duplex US criteria	

Sleep Disorder Management Guidelines

Legend	Text color	Indicates…
Guideline Change Summary	**Blue**	Change to guideline wording (*red for restrictive change)
	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 Sleep Disorder Management.** 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

Polysomnography and Home Sleep Apnea Testing	
Overview Portable testing units that provide respiratory analysis through measurement of peripheral arterial tone (which do not fit neatly into the above classification) are an alternative approach to HSAT. Home sleep apnea studies offer an alternative to PSG for some patients with suspected OSA. This option is more comfortable and convenient for the patient, is less costly and more readily available in regions where the demand for PSG is high. Multiple night home sleep apnea studies may be indicated in some situations. Patients who are age 17 years or younger, have severe chronic obstructive pulmonary disease, advanced congestive heart failure, neuromuscular diseases, or cognitive impairment, are not suitable candidates for home sleep apnea studies **Explanation of change:** Inclusion of devices using peripheral arterial tone as an alternative approach to HSAT	November 15, 2025
Home (Unattended) Sleep Studies **Suspected OSA** Home sleep apnea studies are considered **medically necessary** if the patient meets **ANY** of the following criteria: • Observed apneas during sleep • A combination of **at least TWO of 5 criteria listed below**: ○ Excessive daytime sleepiness evidenced by an Epworth sleepiness scale score greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions ○ Habitual snoring or gasping/choking episodes associated with awakenings ○ Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications) ○ Obesity, defined as a body mass index (BMI) greater than 30 kg/m2 or neck circumference greater than 17 inches in men or greater than 16 inches in women ○ Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease • History of stroke (more than 30 days previously), transient ischemic attack, coronary artery disease, or sustained supraventricular tachycardic or bradycardic arrhythmias in patients who meet **ONE of 5 criteria listed above**	November 15, 2025

• Any of the following conditions which may suggest OSA when the etiology is unclear: right heart failure, polycythemia, sustained supraventricular or ventricular tachyarrhythmia occurring solely during sleep, or pulmonary hypertension **Explanation of change:** Removed contraindication phrasing Expansion of criteria for when etiology is unclear	
Established OSA – follow-up home sleep apnea studies A follow-up home sleep apnea study is considered **medically necessary** for a patient with an established diagnosis of OSA when **ANY** of the following apply: • On one occasion following: ○ Upper airway surgery performed to treat OSA and/or improve compliance with PAP therapy ○ Initiation of use of an oral appliance • To reevaluate the diagnosis of OSA and need for continued CPAP if there is a significant weight loss (defined as 10% of body weight) since the most recent sleep study • Prior to implantation of a hypoglossal nerve stimulator in a patient who has not had a diagnostic study (home or lab) within the preceding 18 months **Explanation of change:** Removed contraindication phrasing	November 15, 2025
In-Lab (Attended) Sleep Studies in Adult Patients (Age 18 Years or Older) **Suspected OSA (in patients with unspecified sleep apnea and nocturnal desaturation, OSA should be suspected and excluded if clinically appropriate)** ***The following criteria apply to individuals with a contraindication to a home sleep apnea study***. *See list of contraindications to home sleep apnea studies.* An in-lab sleep (attended) study is considered **medically necessary** if the patient meets **ANY** of the following criteria and has a contraindication to a home sleep apnea study: • Observed apneas during sleep • A combination of **at least TWO of 5 criteria listed below**: ○ Excessive daytime sleepiness evidenced by an Epworth sleepiness scale score greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions ○ Habitual snoring or gasping/choking episodes associated with awakenings ○ Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications) ○ Obesity, defined as a body mass index (BMI) greater than 30 kg/m2 or neck circumference greater than 17 inches in men or greater than 16 inches in women ○ Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease • History of stroke (more than 30 days previously), transient ischemic attack, coronary artery disease, or sustained tachycardic or bradycardic arrhythmias in patients who meet **ONE of 5 criteria listed above** • Any of the following conditions which may suggest OSA when the etiology is unclear: right heart failure, polycythemia, sustained supraventricular or ventricular tachyarrhythmia occurring solely during sleep, or pulmonary hypertension **Explanation of change:** Expansion of criteria for when etiology is unclear	November 15, 2025

Suspected sleep disorder other than OSA An in-lab supervised sleep study is considered **medically necessary** when there is suspicion of **ANY** of the following: • Central sleep apnea (CSA) – to support the suspicion of CSA in this context, **ONE** of the following must be documented: heart failure, stroke within the preceding 90 days, chronic opiate or narcotic use or Chiari malformation. OSA should be excluded before considering CSA in patients who snore. • Narcolepsy • Nocturnal Seizures • Parasomnia which is likely to result in harm to the patient or others • Idiopathic hypersomnia • Periodic limb movement disorder (PLMD)—to support a suspicion of PLMD in this context, **ONE** of the following must be documented: pregnancy, renal failure, iron deficiency anemia, peripheral neuropathy, use of antidepressant or antipsychotic medications. A diagnosis of PLMD requires that the patient have ongoing hypersomnia or insomnia. Patients with OSA and/or RLS should have these conditions treated before evaluation for PLMD. • Nocturnal desaturation (due to severe COPD or certain restrictive thoracic disorders) **Explanation of change:** Clarifications provided for CSA and PLMD	November 15, 2025
In-Lab (Attended) Sleep Studies in Non-Adult Patients (Age 17 Years or Younger) **Explanation of change:** Age change to clarify non-adult patients	November 15, 2025
Contraindications to Home Sleep Apnea Studies • Age **17** years or younger [no other changes] **Explanation of change:** Age change to clarify non-adult patients	November 15, 2025
Contraindications to APAP [no other changes] **Explanation of change:** Removed age restriction	November 15, 2025
Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing	
Overview **Idiopathic hypersomnia** Daytime sleepiness following adequate (or even prolonged) nocturnal sleep duration and non-refreshing daytime naps are characteristic of idiopathic hypersomnia. Patients with idiopathic hypersomnia may have sleep paralysis and hallucination but cataplexy is absent. Despite prolonged sleep duration, patients with idiopathic hypersomnia display difficult morning awakening, sleep drunkenness and constant somnolence. Idiopathic hypersomnia is rarer than narcolepsy and tends to be more resistant to treatment. A diagnosis of idiopathic hypersomnia requires exclusion of other causes of fatigue and excessive daytime sleepiness including hypothyroidism, depression, obstructive sleep apnea, etc. Patients who have undergone diagnostic testing for OSA and whose AHI is >5 should be adequately treated for OSA before undergoing evaluation for other causes of hypersomnia. **Explanation of change:** Clarification of idiopathic hypersomnia	November 15, 2025
Management of OSA using Auto-Titrating and Continuous Positive Airway Pressure Devices	

Treatment with CPAP is considered medically necessary for a patient aged 18 years or older when BOTH of the following criteria are met: • Home- or lab-based sleep study demonstrates **ONE** of the following: • AHI 15 or higher • AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke • Appropriate CPAP level has been determined **Explanation of change:** Removal of extraneous criteria	November 15, 2025
Treatment with CPAP is considered medically necessary for a patient aged 17 years or younger when BOTH of the following criteria are met: **Explanation of change:** Age change to clarify non-adult patients	November 15, 2025
Treatment with APAP is considered medically necessary for a patient aged 18 years or older when BOTH of the following criteria are met: • Home or lab-based sleep study demonstrates **ONE** of the following: ○ AHI 15 or higher ○ AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke • The patient has no contraindication to the use of APAP (see *APAP contraindications*) **Explanation of change:** Age change to clarify non-adult patients	November 15, 2025
Treatment with APAP is considered medically necessary for a patient aged 17 years or younger when ALL of the following criteria are met: • A lab-based sleep study demonstrating AHI of at least 1 (one) **Explanation of change:** Eliminated titration requirement	November 15, 2025
Ongoing treatment with APAP or CPAP Ongoing treatment with APAP* or CPAP* is considered medically necessary for patients who demonstrate compliance with therapy. Demonstration of compliance is required every 90 days for the first year of therapy and annually thereafter. Compliance is defined as **EITHER** of the following: • Use of the PAP device for at least 4 hours per night on 70% of nights during a consecutive 30-day period within the preceding 90 days • The treating provider (as distinct from the DME provider) attests that the patient is accruing clinical benefit from PAP therapy at current usage levels *Demonstration of compliance is not required for non-adult patients. **Explanation of change:** Clarification that clinical benefit attestation must come from the treating provider	November 15, 2025
Contraindications to APAP • Congestive heart failure • Moderate or severe chronic obstructive pulmonary disease (COPD): FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted **Explanation of change:** Removal of age restriction	November 15, 2025

Bi-Level Positive Airway Pressure Devices	
Ongoing treatment with BPAP Ongoing treatment with BPAP for obstructive sleep apnea* is considered medically necessary for adult patients who demonstrate compliance with therapy. Demonstration of compliance is required for adult patients every 90 days for the first year of treatment and annually thereafter. Compliance is defined as **EITHER** of the following: • Use of the BPAP device for at least 4 hours per night on 70% of nights during a consecutive 30-day period within the preceding 90 days • The treating provider (as distinct from the DME provider) attests that the patient is accruing clinical benefit from PAP therapy at current usage levels *Demonstration of compliance is not required for non-adult patients or when BPAP is used for disorders other than OSA and CSA. **Explanation of change:** Clarification that clinical benefit attestation must come from the treating provider	November 15, 2025
Management of OSA using Oral Appliances	
Overview …It is highly recommended that the decision to use an oral appliance in the management of OSA should follow consultation with a sleep medicine specialist. Custom made oral appliances require a prescription from a medical provider. Oral appliances should be used with caution when there is comorbid temporomandibular joint disease and should be avoided in patients with periodontal disease. **Explanation of change:** Clarification for patients with periodontal disease or temporomandibular joint dysfunction [**TMJ should not be considered an absolute contraindication to oral appliance leading to modification of the blue text as shown above]**	November 15, 2025
Treatment with an Oral Appliance is considered medically necessary for patients aged 16 years or older with severe/ mild or moderate OSA (apnea/hypopnea index [AHI] greater than 30) when ALL of the following criteria are met: • The appliance is a TRD or a Medicare-compliant MRA • The patient does not have periodontal disease or temporomandibular joint dysfunction • **ONE** of the following… **Explanation of change** Use of an oral appliance should be avoided in patients with periodontal disease, or used with caution in those with temporomandibular joint dysfunction	November 15, 2025
Miscellaneous Devices in the Management of OSA and Restless Legs Syndrome	
Guideline Scope This guideline addresses two approaches to the management of obstructive sleep apnea: electronic positional therapy and neuromuscular electrical training of the tongue musculature. In addition, the guideline addresses the use of peroneal nerve stimulation for treatment of restless legs syndrome. **Overview** …To date, no high-quality evidence of benefit has been provided for neuromuscular electrical training as a treatment for OSA. Restless legs syndrome (RLS) is a poorly understood sleep-related disorder in which patients report an urge to move their legs during periods of immobility. The symptoms occur predominantly in the evening or at night and are relieved by movement. Although	November 15, 2025

the pathophysiological mechanisms are not clearly defined, iron deficiency and pregnancy are associated. Treatment consists of avoidance of exacerbating factors, pharmacological intervention (gabapentin enacarbil, gabapentin, pregabalin, extended-release oxycodone), and iron supplementation. Recently, bilateral high-frequency peroneal nerve stimulation has been proposed as a treatment option for patients with refractory RLS. To date, studies supporting this therapy have been small, mostly industry sponsored, and non-blinded (making interpretation of subjective endpoints challenging). **Exclusions** Electronic positional therapy is considered **not medically necessary** in all clinical scenarios. Neuromuscular electrical training of the tongue musculature is considered **not medically necessary** in all clinical scenarios. Peroneal nerve stimulation for management of RLS is considered not medically necessary in all clinical scenarios. **Explanation of change:** Added criteria for restless legs syndrome (RLS). Peroneal nerve stimulation for management of RLS is considered not medically necessary.	

New 2025 Category III CPT Codes

All category III CPT Codes, including new 2025 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.