MASSACHUSETTS

MEDICAL POLICY ANNOUNCEMENTS

Posted May 2024

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

Obstetrics Gynecology
Orthopedics Rehabilitation
Pharmacy
Plastic Surgery

Carelon Clinical Guidelines
Radiology
- Imaging of the Spine
- Imaging of the Extremities
- Vascular Imaging
- Brain Imaging

Sleep Disorder Management
Radiation Oncology
- Radiation Therapy
- Proton Beam Therapy
- Perirectal Hydrogel Spacer for Prostate Radiotherapy

Genetic Testing
- Pharmacogenomics
- Predictive and Prognostic Polygenic Testing (formerly Polygenic Risk Score) Chromosomal Microarrays
- Whole Exome and Whole Genome Sequencing
- Somatic Tumor Testing

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

OBSTETRICS GYNECOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Assisted Reproductive Services	086	**Policy clarified.** Clarifications made to donor sperm evaluation criteria. Uterine cavity evaluation timeframe increased from 12 months to 18 months for FET.	May 1, 2024	Commercial	Prior authorization is still required.
Identification of Microorganisms	555	**Policy clarified.** Code 0402U added to policy.	May 1, 2024	Commercial Medicare	No action required.

Using Nucleic Acid Probe					
Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis	711	**Policy clarified.** Code 0402U transferred to MP 555 Identification of Microorganisms Using Nucleic Acid Probe.	May 1, 2024	Commercial Medicare	No action required.

ORTHOPEDICS REHABILITATION

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment Noncovered Services List	400	**Policy clarified.** ROMTech PortableConnect ® Orthopedic Rehabilitation Technology added.	April 9, 2024	Commercial Medicare	No action required. This is not a covered service.
Dynamic Low-Load Prolonged-Duration Stretch Devices	405	**New medical policy** describing medically necessary and investigational indications.	August 1, 2024	Commercial	Prior authorization is not required.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Gene Therapies for Sickle Cell Disease	050	**Policy revised** to include coverage for Lyfgenia™ (Lovotibeglogene autotemcel) for treatment of sickle cell disease. Prior Authorization Request Form for Casgevy, #055 Prior Authorization Request Form for Lyfgenia, #079	April 1, 2024	Commercial Medicare	Prior authorization is still required.

Medical Technology Assessment Noncovered Services	400	**Policy clarified.** Lyfgenia™ (Lovotibeglogene autotemcel) for treatment of sickle cell disease removed.	April 1, 2024	Commercial Medicare	See MP 050 Gene Therapies for Sickle Cell Disease
Medicare Advantage Part B Step Therapy	020	**Policy revised.** Eylea HD (aflibercept) added to the Drug Class "Vascular Endothelial Growth Factor (VEGF) Inhibitors" as a second line agent.	May 1, 2024	Medicare	Prior authorization is still required.
Injectable Asthma Medications	017	**Policy revised** to add prescriber requirements for the medications in the policy. Requirements will apply to new or renewed prior authorizations only. No change for active authorizations.	August 1, 2024	Commercial Medicare	Prior authorization is still required.

PLASTIC SURGERY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Surgical and Non-surgical Treatment of Gynecomastia	661	**Policy clarified.** References added. Policy statements unchanged.	May 1, 2024	Commercial Medicare	Prior authorization is not still required.

Carelon

Radiology Imaging Guidelines

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

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

Carelon Guideline	Policy Change Summary	Effective Date
Imaging of the Spine		
Definitions	**General prerequisites for spine imaging:** ○ **Physical therapy requirement includes ANY** of the following: ▪ Physical therapy rendered by a qualified provider of physical therapy services ▪ Supervised home treatment program that includes **ALL** of the following: • Participation in a patient-specific or tailored program • Initial active instruction by physician or allied health provider with redemonstration of patient ability to perform exercises. **Explanation of change** Expanded definition of professional qualified to supervise a home exercise program	October 20, 2024
Perioperative and Periprocedural Imaging	**Postoperative and postprocedural imaging**, including delayed hardware failure or healing related to prior surgery, not otherwise specified **Explanation of change** Removed the preprocedural component as preprocedural requests should be reviewed based on a more specific indication.	October 20, 2024
Pain indications	**Non-specific low back pain (lumbar)** ***PEDIATRIC*** 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 • Pain with neurologic findings suggesting lumbar nerve root or cord compression that has not previously been imaged or has progressed since imaging was performed **Explanation of change** Removed radiograph requirement in pediatric patients with evidence of nerve root or cord compression	October 20, 2024
	Imaging of the Extremities	
Definitions	**General prerequisites for extremity imaging:** ○ **Physical therapy requirement includes ANY** of the following: ▪ Physical therapy rendered by a qualified provider of physical therapy services ▪ Supervised home treatment program that includes **ALL** of the following: • Participation in a patient-specific or tailored program • Initial active instruction by physician or allied health provider with redemonstration of patient ability to perform exercises. **Explanation of change**	October 20, 2024

	Expanded definition of professional qualified to supervise a home exercise program	
Infection	**Soft tissue infection** Advanced imaging is considered medically necessary for diagnosis and management in **ANY** of the following scenarios: **Explanation of change** Removed requirement for initial evaluation with radiographs or ultrasound **Osteomyelitis** Advanced imaging is considered medically necessary for diagnosis and management when radiographs are nondiagnostic or not sufficient to guide treatment. **Septic arthritis** Advanced imaging is considered medically necessary for diagnosis and management when radiograph, ultrasound, or arthrocentesis is nondiagnostic or not sufficient to guide treatment. **Explanation of change** Removed ultrasound and arthrocentesis as possible preliminary studies before advanced imaging, as those studies are more appropriate for septic arthritis Separated osteomyelitis and septic arthritis; no change in criteria for septic arthritis	October 20, 2024

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 cortex; plateau)
	  ○ 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)
	• Evaluation of supracondylar, intra-articular, or Salter-Harris (growth plate) fractures when radiographs are insufficient for management
	• 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
	Explanation of change
	Clarified language around appropriateness of CT to better align with the guideline criteria; no change in intent
		October 20, 2024

Ligament and Tendon Derangement of the Upper Extremity	**Rotator cuff tear**
	Advanced imaging is considered medically necessary for diagnosis of new or recurrent tear when **ALL** of the following apply:
	• Radiographs or ultrasound are nondiagnostic
	• At least one positive sign to support the diagnosis of rotator cuff tear has been demonstrated
	• EITHER of the following:
	  ○ At least one positive sign of a complete rotator cuff tear
	  ○ Failure of at least 6 weeks of conservative management
	Explanation of change
	Modified language to clarify that this indication can be used for both new and recurrent tears
		October 20, 2024

Miscellaneous Conditions	**Paget disease** Advanced imaging is considered medically necessary to evaluate for malignant transformation of Pagetoid lesions **IMAGING STUDY** • CT upper extremity; CT lower extremity • MRI upper extremity (joint or non-joint); MRI lower extremity **Explanation of change** Removed guideline language that applies to bone scintigraphy rather than advanced imaging	October 20, 2024
	Vascular Imaging	

Brain, Head and Neck	**Aneurysm, intracranial**
	Advanced imaging is considered medically necessary in **ANY** of the following scenarios:
	Screening in ANY of the following high-risk groups:
	• Two (2) or more first-degree relatives with intracranial aneurysm or subarachnoid hemorrhage
	• Condition associated with an increased risk of intracranial aneurysm (examples include autosomal dominant polycystic kidney disease, Ehlers-Danlos syndrome type IV)
	• Known fibromuscular dysplasia
	Diagnosis of clinically suspected intracranial aneurysm:
	• CT or MRI findings suspicious for aneurysm
	• Neurologic signs or symptoms (including headache) suggestive of intracranial aneurysm with ANY of the following:
	  ○ At least one first degree relative with intracranial aneurysm or subarachnoid hemorrhage
	  ○ Presence of a condition associated with an increased risk of intracranial aneurysm (such as autosomal dominant polycystic kidney disease, Ehlers-Danlos syndrome type IV)
	Explanation of change
	Clarification to include conditions associated with a higher risk of IA (as referenced in the original citation)
		October 20, 2024

Stenosis or occlusion, vertebral or basilar arteries	**Stenosis or occlusion, vertebral or basilar arteries** **IMAGING STUDY** • CTA or MRA head • CTA or MRA neck **Explanation of change**	October 20, 2024

	Removing Duplex ultrasound as imaging option (suboptimal modality for full vertebral/basilar artery evaluation).	

Stroke or transient ischemic attack (TIA), intracranial evaluation	**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:
	• Acute (7 days or less) stroke/TIA in ANY of the following scenarios:
	  ○ Acute stroke in an interventional candidate
	  ○ Evidence of acute ischemia or infarct on brain imaging
	  ○ Evaluation following acute TIA
	• Subacute (within 30 days) stroke/TIA in **EITHER** of the following scenarios:
	  ○ Signs or symptoms attributable to the anterior circulation, when the presence of intracranial stenosis will lead to use of dual antiplatelet therapy
	  ○ Signs or symptoms other than syncope attributable to the posterior circulation
	• Chronic (30 days or more) stroke/TIA with signs or symptoms other than syncope attributable to the posterior circulation
	Explanation of change
	Addition for chronic posterior circulation presentations (CTA/MRA neck allowed below, intracranial eval needed for full extent).
		October 20, 2024

Venous thrombosis or compression, intracranial	**Venous thrombosis or compression, intracranial** **IMAGING STUDY** • CTA head • MRA head • CT brain or MRI Brain when CTA/MRA head cannot be performed **Explanation of change** Downgrade of CT Head/MRI Brain modality (suboptimal for eval of venous thrombus compared to CTV/MRV)	October 20, 2024
Abdomen and pelvis	**Hematoma/hemorrhage within the abdomen or pelvis** **IMAGING STUDY** • CTA abdomen and/or pelvis • CT abdomen and/or pelvis; alternative to CTA **Explanation of change** Clarification of title; removal of MRA modality (suboptimal/not really utilized for indication)	October 20, 2024
IVC and iliac vein evaluation	**IVC and iliac vein evaluation** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • Suspected or established thrombus in the abdomen or pelvis, including IVC/iliac veins • Suspected or established IVC or iliac vein mass • Suspected or established external compression or stenosis of the IVC or iliac veins **Explanation of change** Clarification of intent for compression/stenosis	October 20, 2024
Upper extremity	**Vascular access procedures** Vascular imaging is considered medically necessary in **ANY** of the following scenarios:	October 20, 2024

	• Evaluation of native arteries prior to arteriovenous fistula or graft for dialysis access
	• Planned harvest of the radial artery (e.g., for CABG)
	• Complications of a vascular access procedure suggested by **ANY** of the following:
	  ○ Pulsatile mass, bruit, or thrill at the access site
	  ○ Significant (more than expected post procedure) hematoma or abnormal skin changes at the access site
	  ○ Severe (more than expected post procedure) pain at the access site
	  ○ Signs of ischemia or embolism in the involved extremity (such as ischemic or discolored fingers, livedo reticularis)
	Explanation of change
	Clarification of complication.	

Lower extremity	**Peripheral arterial disease (PAD)** Diagnosis of suspected PAD **in EITHER** of the following scenarios: • Any sign or symptom with inconclusive physiologic testing (including exercise testing or segmental pressure measurements) • Signs or symptoms of critical limb ischemia (including ischemic rest pain, ischemic skin changes or ulceration, or non-healing wounds or gangrene) **Explanation of change** Diagnostic indications: Updated physiologic testing parameters Allowance for ischemic signs/symptoms at presentation, in alignment with ACR Appropriateness Criteria	October 20, 2024
Vascular access procedures	**Vascular access procedures** Vascular imaging is considered medically necessary for suspected complications of a vascular access procedure suggested by **ANY** of the following: • Pulsatile mass, bruit, or thrill at the access site • Significant (more than expected post procedure) hematoma or abnormal skin changes at the access site • Severe (more than expected post procedure) pain at the access site • Signs of ischemia or embolism in the involved extremity (such as ischemic or discolored fingers, livedo reticularis) **Explanation of change** Clarification of complication.	October 20, 2024
	Brain Imaging	
Neuro-degenerative conditions	**Movement disorders (Adult only)** **IMAGING STUDY** • CT brain • MRI brain (preferred) **Explanation of change** Removed the exclusion of MRI prior to MR-guided focused ultrasound for essential tremor; many protocols for MRgFUS require a diagnostic MRI brain prior to the procedure for anatomic localization	October 20, 2024
Neuro-	**Neurocognitive disorders (Adult only)** **MRI brain (preferred) or CT brain** Management:	October 20, 2024

cognitive disorders (Adult only)	• Evaluation of rapidly progressive symptoms • In patients being treated with lecanemab, prior to the 5th, 7th, and 14th infusions **Amyloid PET imaging** Diagnosis: One-time evaluation 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) • Lecanemab therapy is being considered Management: Not indicated **Explanation of change** Added allowance for amyloid beta PET imaging in the initial diagnosis of Alzheimer dementia for patients in whom lecanemab therapy is being considered.	

Sleep Disorder Management Guidelines

Legend	**Text color**	**Indicates…**
Guideline Change Summary	**Blue**	Change to guideline wording
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		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

Carelon Guideline	Policy Change Summary	Effective Date
Definitions	Established diagnosis of obesity hypoventilation syndrome defined as a body mass index (BMI) greater than 30 kg/m2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology, or medications. Documentation of hypoventilation requires **ANY** of the following: • Increase in arterial PCO2 (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes • Greater than 10 mmHg increase in arterial PCO2 (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes • Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 consecutive minutes of nocturnal recording time (minimum recording time of 2 hours), recorded while breathing the patient's prescribed FiO2	October 20, 2024

	Explanation of change Expanded requirement for documentation of hypoventilation (also appears in contraindications for APAP)	
Hypersom-nolence	Excessive daytime sleepiness **Explanation of change** More expansive definition	October 20, 2024

Established OSA	**Home sleep apnea studies**
	A follow-up home sleep apnea study is considered medically necessary for a patient with an established diagnosis of OSA and no contraindication to a home sleep apnea study when **EITHER** 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
	Added criteria to make more expansive
		October 20, 2024

In-Lab Studies (Attended) Sleep Studies in Adult Patients (Age 19 Years or Older)	**In-Lab Studies (Attended) Sleep Studies in Adult Patients (Age 19 Years or Older)**
	A follow-up in-lab sleep study is considered medically necessary for a patient with an established diagnosis of OSA if **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 significant weight loss (defined as 10% of body weight) since the most recent sleep study in a patient with contraindications to home sleep apnea studies
	• 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
	• To optimize device settings on one occasion following insertion of a hypoglossal or phrenic nerve stimulatorBrain
	Explanation of change
	Added criteria to make more expansive
		October 20, 2024

In-Lab (Attended) Sleep Studies in non-Adult Patients (Age 18 Years or Younger)	**In-Lab (Attended) Sleep Studies in non-Adult Patients (Age 18 Years or Younger)** A follow-up in-lab sleep study is considered medically necessary in **ANY** of the following scenarios: • A patient with established OSA continues to exhibit persistent snoring or other symptoms of sleep disordered breathing despite PAP adherence as defined by CMS criteria (use of PAP for at	October 20, 2024

	least 4 hours per night on 70% of nights during a consecutive 30-day period) • The patient has undergone adenotonsillectomy or other upper airway surgery more than 8 weeks previously for management of established OSA • 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 • To reevaluate the diagnosis of OSA and need for continued PAP if there is significant weight loss (defined as 10% of body weight) since the most recent sleep study • To titrate CPAP or BPAP in a patient whose diagnostic study confirms that the patient is a candidate for positive airway pressure therapy and split-night study has not been performed or was inadequate • The initial sleep study has led to a diagnosis other than OSA and the repeat study is requested because of a change in clinical status or to assess efficacy after a change in therapy **Explanation of change** Added criteria to make more expansive	
Contra-indications to APAP titration	• Age 18 years or younger • Congestive heart failure • Moderate or severe chronic obstructive pulmonary disease: FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted • Chronic opiate use • Use of supplemental oxygen for 24 hours daily • Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour) • Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis) • Obesity hypoventilation syndrome defined as a body mass index (BMI) greater than 30 kg/m2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology, or medications. Documentation of hypoventilation requires **ANY** of the following: ○ Increase in arterial PaCO2 (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes ○ Greater than 10 mmHg increase in arterial PaCO2 (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes ○ Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 consecutive minutes of nocturnal recording time (minimum recording time of 2 hours), recorded while breathing the patient's prescribed FiO2 **Explanation of change** Added contraindication for use of supplemental oxygen Expanded documentation requirement for hypoventilation	October 20, 2024
Multiple Sleep Latency Testing and	**Initial MSLT and/or MWT are considered medically necessary for suspected narcolepsy when BOTH of the following criteria are met:**	October 20, 2024

Maintenance of Wakefulness Testing	• Excessive daytime sleepiness has been present for at least 8 weeks • The patient has at least **ONE** of the following: ○ Disrupted nocturnal sleep ○ Cataplexy ○ Hallucinations (hypnagogic or hypnopompic) ○ Sleep paralysis ○ The patient has undergone polysomnography (PSG) since the onset of symptoms, and symptoms persist despite adequate treatment of obstructive sleep apnea (if present) **Explanation of change** Incorporated a more expansive definition of daytime sleepiness. Removed home sleep apnea testing (HSAT) as an option in medical necessity of MSLT/MWT for suspected narcolepsy.	
Management of OSA using Implanted Hypoglossal Nerve Stimulators	Treatment with HNS is considered medically necessary for adolescent and young adult patients with Down syndrome and OSA who meet ALL of the following criteria: • Age between 13 and 21 years • AHI or RDI between 10 and 50 with less than 25% central apneas after prior adenotonsillectomy (or contraindication thereto) **Explanation of change** Narrowed age range (raised lower limit to 13) for HNS in individuals with Down syndrome and OSA to align with age range suggested by FDA Clarification	October 20, 2024
Management of OSA (Miscellaneous Devices)	**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 **Explanation of change** New section for miscellaneous devices in the management of OSA. Electronic positional therapy and neuromuscular electrical training of the tongue musculature are considered not medically necessary due to lack of high-quality evidence.	

Radiation Oncology Guidelines

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Guideline Change Summary	**Blue**	Change to guideline wording
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The following updates will apply to the Carelon Clinical Appropriateness **Guidelines for Radiation Oncology**. You may access and download a copy of the current guidelines here. For questions related to the guidelines, please contact Carelon via email at MedicalBenefitsManagement.guidelines@carelon.com

Carelon Guideline	Policy Change Summary	Effective Date
Radiation Therapy		
Breast cancer	**Breast cancer** Hyperthermia is appropriate for breast cancer when the following condition is met: • For individuals with a chest wall recurrence after prior radiation therapy to the chest or breast. **Explanation of change** Removed hyperthermia for breast cancer due to low utilization.	October 20, 2024
Liver cancer	**Hepatocellular Carcinoma** Stereotactic Body Radiation Therapy (SBRT) is appropriate when **ANY** of the following conditions are met: • As palliative treatment for individuals with liver-related symptoms • As treatment of new or recurrent HCC unsuitable for surgery, embolization, or TACE, when these therapies have been done and have failed, or are contraindicated, when **BOTH** of the following conditions are met: ○ ≤ 5 HCC lesions with a sum of < 20 cm ○ Patients with Child-Pugh category A or B OR Barcelona Clinic Liver Cancer Stage A, B, or C disease • To treat a previously irradiated field **Explanation of change** Clarification to align with the inclusion criteria of the RTOG 1112 protocol. As per Appendix IV of the protocol. This is not a significant change in clinical indication.	October 20, 2024
	Proton Beam Therapy	
Proton Beam Therapy	Reaffirmed with no changes	October 20, 2024
	Perirectal Hydrogel Spacer for Prostate Radiotherapy	
Perirectal Hydrogel Spacer for Prostate Radiotherapy (reaffirmed with no changes	Reaffirmed with no changes	October 20, 2024

Genetic Testing Guidelines

Legend	Text color	Indicates…
Guideline Change Summary	**Blue**	Change to guideline wording
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		Changes expected to be…
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	Red	More restrictive on appropriateness
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The following updates will apply to the Carelon Clinical Appropriateness **Guidelines for Genetic Testing**.

You may access and download a copy of the current guidelines here. For questions related to the guidelines, please contact Carelon via email at MedicalBenefitsManagement.guidelines@carelon.com

Carelon Guideline	Policy Change Summary	Effective Date
	Chromosomal Microarray Analysis	

Chromosomal Microarray Analysis	General Recommendations
	
	Genetic Counseling
	Counseling is encouraged prior to chromosomal microarray analysis (CMA) and should include ALL of the following components:
	• Interpretation of personal and family medical histories to provide a risk assessment for disease occurrence or recurrence
	• Education about inheritance patterns, genetic testing, disease management, prevention, risk reduction, and resources
	• Counseling to promote informed choices and adaptation to the risk or presence of a genetic condition
	• Counseling for the psychological aspects of genetic testing
	• Counseling should include the following details:
	  ○ Limitations of the testing used
	  ○ A negative result does not indicate heritable risk is zero or low
	  ○ Identification of incidental and inconclusive results called variants of uncertain significance is possible
	  ○ Modifications to genetic variants' pathogenicity interpretations can occur, and patients may be recontacted with reclassified results in the future
	Note: Post-test counseling should be performed for any genetic test result.
	Explanation of change
	Clarified recommendations for Genetic Counseling.
		October 20, 2024

Postnatal evaluation	**Postnatal evaluation** Chromosomal microarray analysis (CMA) is considered medically necessary as a first-line test in the initial postnatal evaluation of individuals with ANY of the following: • Multiple congenital anomalies without an established diagnosis • Congenital or early onset epilepsy (before age 3 years) without suspected environmental causes • Autism spectrum disorder with no identifiable cause (idiopathic) • Developmental delay or intellectual disability with no identifiable cause (idiopathic) **Explanation of change** Clarifications.	October 20, 2024
Prenatal evaluation	**Prenatal evaluation** Chromosomal microarray analysis is considered medically necessary for the prenatal evaluation of a fetus for **ANY** of the following: • Structural fetal anomaly noted on ultrasound • Fetal demise or history of 2 or more miscarriages	October 20, 2024

	• Individuals undergoing invasive diagnostic testing based on advanced maternal age or positive findings on other screening tests **Explanation of change** Clarification.	
	Whole Exome and Whole Genome Sequencing	
Whole Exome Sequencing and Whole Genome Sequencing	**Whole Exome Sequencing** Whole exome sequencing (WES) is considered medically necessary in the evaluation of an individual[1] who meets **ALL** of the following criteria: • **ONE** of the following criteria is met: ○ Multiple anomalies (i.e., structural and/or functional) apparent before one year of age not suggestive of a diagnosis detectable with a targeted test[2] ○ For the evaluation of a fetus with abnormal fetal anatomic findings which are characteristic of a genetic abnormality and no diagnostic findings were found on karyotype and/or chromosomal microarray testing ○ Developmental delay, autism spectrum disorders, or intellectual disability with onset prior to 18 years of age with no identifiable cause (idiopathic) ○ Congenital or early onset epilepsy (before age 3 years) without suspected environmental etiology • When the results of testing would confirm or establish a clinical diagnosis • Counseling, which encompasses **ALL** of the following components, has been performed: ○ Interpretation of family and medical histories to provide a risk assessment for disease occurrence or recurrence ○ Education about inheritance patterns, genetic testing, disease management, prevention, and resources ○ Counseling to promote informed choices and adaptation to the risk or presence of a genetic condition ○ Counseling for the psychological aspects of genetic testing ○ Counseling should include the following details: ▪ Limitations of the testing used ▪ A negative result does not indicate heritable risk is zero or low ▪ Identification of incidental secondary findings and inconclusive results called variants of uncertain significance is possible ▪ Modifications to genetic variants' pathogenicity interpretations can occur, and patients may be recontacted with reclassified results in the future ○ Post-test counseling should be performed for genetic test results Notes: 1. WES may include comparator WES testing of the biologic parent(s) or sibling (duo or trio testing) of the affected individual. 2. Chromosomal microarray (CMA) or targeted gene panel test.	October 20, 2024

<table>
<tr><td></td><td>Explanation of change
Expanded WES criteria to include congenital or early onset epilepsy (before age 3) without suspected environmental etiology.
Added other clarifications for WES including well-delineated genetic syndrome in criterion for multiple anomalies and details for counseling.</td><td></td></tr>
<tr><td colspan="3">Pharmacogenomic Testing</td></tr>
<tr><td>Pharmaco-genomic Testing</td><td>For each of the following FDA-approved therapies and associated biomarkers (see Table 1), one genotyping for the appropriate biomarker is considered medically necessary when ALL the following conditions are met:
• The medication for which genotyping is being done is the most appropriate treatment for the individual’s underlying condition
• The pharmacogenomic test has demonstrated analytical and clinical validity and clinical utility for the individual, including consideration of the frequency of relevant alleles in the individual’s subgroup (when applicable)
• The biomarker testing is focused on the specific genetic polymorphisms relevant to guiding treatment for the individual’s condition and expected treatment

<table><tr><th>Biomarker</th><th>Drug</th><th>Therapeutic Area</th></tr><tr><td>ApoE ε4</td><td>lecanemab</td><td>Neurology</td></tr><tr><td>CFTR</td><td>vacaftor</td><td>Pediatrics</td></tr><tr><td>CYP2C19</td><td>clopidogrel</td><td>Cardiology</td></tr><tr><td>CYP2C9</td><td>siponimod</td><td>Neurology</td></tr><tr><td>CYP2D6</td><td>eliglustat</td><td>Pediatrics</td></tr><tr><td>CYP2D6</td><td>tetrabenazine</td><td>Neurology</td></tr><tr><td>G6PD</td><td>rasburicase</td><td>Hematology</td></tr><tr><td>G6PD</td><td>tafenoquine, primaquine</td><td>Infectious Diseases</td></tr><tr><td>HLA-*1502</td><td>carbamazepine, oxcarbazepine</td><td>Neurology</td></tr><tr><td>HLA-*5701</td><td>abacavir</td><td>Infectious Diseases</td></tr><tr><td>HLA-*58:01</td><td>allopurinol</td><td>Rheumatology</td></tr><tr><td>NAGS</td><td>carglumic acid</td><td>Gastroenterology</td></tr><tr><td>POLG</td><td>divalproex sodium, valproic acid</td><td>Neurology</td></tr><tr><td>TPMT</td><td>mercaptopurine thioguanine</td><td>Hematology</td></tr></table>Explanation of change
Added APOE testing.</td><td>October 20, 2024</td></tr>
<tr><td></td><td>Predictive and Prognostic Polygenic Testing (formerly Polygenic Risk Score)</td><td></td></tr>
<tr><td>Predictive and Prognostic Polygenic Testing (formerly Polygenic Risk Score)</td><td>Exclusions
Polygenic risk scores
The use of polygenic risk scores is considered not medically necessary for all indications.

Polygenic expression prognostic testing</td><td>October 20, 2024</td></tr>
</table>

	Unless otherwise indicated in other Carelon MBM guidelines (i.e., Somatic Tumor Testing and Genetic Testing for Inherited Conditions), the use of polygenic expression prognostic testing is considered **not medically necessary** for all indications. **Multivariable prognostic genetic testing** The use of multivariable prognostic genetic testing is considered **not medically necessary** for all indications. **Explanation of change** Expanded guideline scope with the addition of polygenic expression prognostic testing and multivariable prognostic genetic testing (essentially clarifications). Moved to Exclusions as these tests are considered not medically necessary.	
	Somatic Tumor Testing	

Breast Cancer	**Localized breast cancer**
	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 Breast Cancer Prognostic Gene Signature Assay, or the Breast Cancer Index when **ALL** of the following criteria are met:
	• Surgery has been performed and a full pathological evaluation of the specimen has been completed
	• Histology is ductal, lobular, mixed, or metaplastic
	• 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
	• 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)
	*Note: 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.
	
	Gene expression profiling with the Oncotype DX or MammaPrint… [no change to criteria]
		October 20, 2024

	Breast cancer gene expression profiling is not medically necessary to guide decision-making for extended-adjuvant endocrine therapy. **Explanation of change** Clarified gene expression profiling is to guide adjuvant therapy for localized breast cancer.	

New 2024 Category III CPT Codes

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

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

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

Definitions

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

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

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

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