MASSACHUSETTS

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Medical Policy Updates

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May 2024

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 Using Nucleic Acid Probe	555	**Policy clarified.** Code 0402U added to policy.	May 1, 2024	Commercial Medicare	No action required.
Multitarget Polymerase Chain Reaction	711	**Policy clarified.** Code 0402U transferred to MP 555 Identification of	May 1, 2024	Commercial Medicare	No action required.

Testing for Diagnosis of Bacterial Vaginosis		Microorganisms Using Nucleic Acid Probe.			

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	020	**Policy revised.** Eylea	May 1,	Medicare	Prior

Advantage Part B Step Therapy		HD (aflibercept) added to the Drug Class "Vascular Endothelial Growth Factor (VEGF) Inhibitors" as a second line agent.	2024		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:	October 20, 2024

	• 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	
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** Expanded definition of professional qualified to supervise a home exercise program	October 20, 2024
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	October 20, 2024

	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	
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** Removing Duplex ultrasound as imaging option (suboptimal modality for full vertebral/basilar artery evaluation).	October 20, 2024
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	October 20, 2024

	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).	
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: • 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.	October 20, 2024
Lower extremity	**Peripheral arterial disease (PAD)** Diagnosis of suspected PAD **in EITHER** of the following scenarios: • Any sign or symptom with inconclusive physiologic testing	October 20, 2024

	(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	
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-cognitive disorders (Adult only)	**Neurocognitive disorders (Adult only)** **MRI brain (preferred) or CT brain** Management: • 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.	October 20, 2024

Sleep Disorder Management 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
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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 **Explanation of change** Expanded requirement for documentation of hypoventilation (also appears in contraindications for APAP)	October 20, 2024
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	October 20, 2024

	the preceding 18 months **Explanation of change** Added criteria to make more expansive	
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 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	October 20, 2024
Contra-indications to APAP titration	• Age 18 years or younger • Congestive heart failure • Moderate or severe chronic obstructive pulmonary disease:	October 20, 2024

	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	
Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing	**Initial MSLT and/or MWT are considered medically necessary for suspected narcolepsy when BOTH of the following criteria are met:** • 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.	October 20, 2024
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**	October 20, 2024

	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	
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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Explanation of Change	**Green**	More expansive on appropriateness
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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**	October 20, 2024

	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.	
	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…**
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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	October 20, 2024

	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.	
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 • Individuals undergoing invasive diagnostic testing based on advanced maternal age or positive findings on other screening tests **Explanation of change** Clarification.	October 20, 2024
	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	October 20, 2024

	• 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. **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.	
Pharmacogenomic Testing		
Pharmaco-genomic Testing	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 **Biomarker** | **Drug** | **Therapeutic Area**	October 20, 2024

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

	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] 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.	

April 2024

BEHAVIORAL HEALTH

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Transcranial Magnetic Stimulation as a Treatment of Depression	297	**Policy revised.** Prior authorization will be required for Commercial PPO on effective date.	July 1, 2024	Commercial	Prior authorization is required.

CARDIOLOGY

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

Transcatheter Aortic-Valve Implantation for Aortic Stenosis	392	**Policy revised.** For TAVI and valve-in-valve TAVI, the criterion of left ventricular ejection fraction greater than 20% was removed. A statement was added for consideration of individuals who may be at high risk of open surgery but not demonstrated on Society of Thoracic Surgeons risk score.	July 1, 2024	Commercial	No action required.
Cardiovascular Risk Panels	664	**Policy 664 retired**. Cardiovascular Risk Panels transferred to MP 283 Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease.	April 1, 2024	Commercial	No action required.
Measurement of Lipoprotein-Associated Phospholipase A2 - Lp-PLA2 - in the Assessment of Cardiovascular Risk	558	**Policy 558 retired.** Measurement of Lipoprotein-Associated Phospholipase A2 in the Assessment of Cardiovascular Risk is transferred to MP 283 Novel Biomarkers in Risk Assessment and Management of Cardiovascular Disease.	April 1, 2024	Commercial	No action required.
Biomarker Testing in Risk Assessment and Management of Cardiovascular Disease	283	**Policy clarified.** Statements from MP 558 Measurement of Lipoprotein-Associated Phospholipase A2 in the Assessment of Cardiovascular Risk and MP 664 Cardiovascular Risk Panels were combined into MP 283.	April 1, 2024	Commercial	No action required.

NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment	400	**Policy clarified.** Multiple Sclerosis Disease Activity (MSDA)	April 1, 2024	Commercial Medicare	No action required.

Non-Covered Services List		Test added to the narrative section of policy 400.			This is not a covered service.

NEUROSURGERY ORTHOPEDICS

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Intraosseous Basivertebral Nerve Ablation	485	Policy inclusion criteria **revised**.	July 1, 2024	Commercial	Prior authorization is still required.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Botulinum Toxin Injections	006	**Policy revised.** Myobloc, Xeomin and Daxxify are being moved to Non-Formulary Non-Covered in the policy.	July 1, 2024	Commercial	Prior authorization is still required.
Immunomodulators for Skin Conditions	010	**Policy revised.** Rinvoq criteria is being changed. A trial of topical corticosteroid and topical calcineurin inhibitor is required.	July 1, 2024	Commercial	Prior authorization is still required.
Injectable Asthma Medications	017	**Policy revised to** include dose and frequency requirement for the medications in the policy to coincide with the medical claim system edits.	July 1, 2024	Commercial	Prior authorization is still required.
Anti-Migraine Policy	021	**Policy revised.** Qulipta is being moved to covered. A note is being added that Vyepti is part of the Medical Utilization Management program.	July 1, 2024	Commercial	Prior authorization is still required.
Medical Benefit Prior Authorization Medication List	034	**Policy revised.** Vyepti is being added to the Medical Utilization Management list.	July 1, 2024	Commercial	Prior authorization is still required.
Supportive Care	105	**Policy revised.**	July 1,	Commercial	Prior

Treatments for Patients with Cancer		These drugs are being moved to Non-Formulary Non-Covered drugs in the policy: Nivestym, Releuko, Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, and Udenyca.	2024	Medicare	authorization is still required.
Hepatitis C Medication Management	344	**Policy revised.** Vosevi is being added to Non-Formulary Non-Covered. Ledipasvir/sofosbuvir and sofosbuvir/velpatasvir are being moved to covered in the policy.	July 1, 2024	Commercial	Prior authorization is still required.
Topical Ocular Hydrating Agents	426	**Policy revised.** Lacrisert is being added to the policy.	July 1, 2024	Commercial	Prior authorization is still required.
Medical Utilization Management (MED UM) & Pharmacy Prior Authorization Policy	033	**Policy revised.** Dupixent for atopic dermatitis (eczema) criteria is being changed. A trial of topical corticosteroid and topical calcineurin inhibitor is required.	July 1, 2024	Commercial	Prior authorization is still required.
Phosphodiesterase Type-5 Inhibitors for Pulmonary Arterial Hypertension	036	**Policy retired.** These drugs are covered.	July 1, 2024	Commercial	No action required.
Benign Prostatic Hyperplasia - BPH	040	**Policy retired.** These drugs are covered.	July 1, 2024	Commercial	No action required.

UROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment Non-Covered Services List	400	**Policy clarified.** Bladder Voiding Pressure Study / Penile Cuff Pressure Test (Urocuff) added to the narrative section of	March 1, 2024	Commercial Medicare	No action required. This is not a covered service.

		policy 400.			

March 2024

BEHAVIORAL HEALTH PSYCHIATRY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Neuropsycho-logical and Psychological Testing	151	Policy clarified to specify that a typical course of neuropsychological testing can be completed in 10 hours.	March 1, 2024	Commercial	Prior authorization is still required for Commercial Managed Care (HMO and POS). Prior authorization is not required for Commercial PPO and Indemnity.

DERMATOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Fractional Carbon Dioxide (CO2) Laser Ablation Treatment of Hypertrophic Scars or Keloids for Functional Improvement	039	**New medical policy** describing investigational indications	June 1, 2024	Commercial Medicare	No action required. This is not a covered service.

NEUROSURGERY ORTHOPEDICS

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Interspinous Fixation (Fusion) Devices	436	**Policy clarified** to include a list of interspinous fixation devices cleared for marketing by the FDA.	February 7, 2024	Commercial Medicare	No action required. This is not a covered service.
Intraoperative Neurophysiolog	211	**Policy clarified.** Added cross-reference to	February 12, 2024	Commercial	Prior authorization is

ic Monitoring Sensory-Evoked Potentials, Motor-Evoked Potentials, EEG Monitoring		related policy #701 regarding electromyography (EMG), and coding clarification regarding the need for both EMG CPT code and intraoperative monitoring code if EMG is being used for intraoperative monitoring.			still required.
Electro-myography and Nerve Conduction Studies	701	**Policy clarified.** Added statement regarding medical necessity as part of intraoperative neurophysiologic monitoring and cross-references to related policy #211 and regarding CPT coding.	February 12, 2024	Commercial	Prior authorization is not required.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Glucagon-like Peptide-1 (GLP-1) Agonists Drugs	O56	New medical policy describing medically necessary and investigational indications. GLP-1 agonists will be removed from policy #041 Diabetes Step Therapy and transferred to policy #056.	July 1, 2024	Commercial	Prior authorization is required.
Medicare Advantage Part B Medical Utilization Management	125	Aduhelm removed from Part B Medical Utilization Management.	March 1, 2024	Medicare	Providers will not be required to submit a Prior Authorization request for the use of Aduhelm.
Gene Therapies for Sickle Cell Disease	050	**Casgevy™** **New medical policy** describing medically necessary and investigational indications. Gene Therapies for Sickle Cell Disease	January 1, 2024	Commercial Medicare	Prior authorization is required.

		Prior Authorization Request Form for Casgevy ™ (Exagamglogene autotemcel), #055 **Lyfgenia™** **New medical policy** describing non-coverage. Lyfgenia does not meet guideline #4 of BCBSMA policy. ▪ 350 Medical Technology Assessment Guidelines; ▪ 400 Medical Technology Assessment Investigational (Non-covered) Service List			
Heart Failure and Hypertrophic Cardio-myopathy (HCM) Policy	063	**Policy revised** to add a new step therapy table for kidney disease and other risk factors**.** **Policy title changed** to: Heart Failure, Chronic Kidney Disease and Hypertrophic Cardiomyopathy (HCM) Policy.	April 1, 2024	Commercial	Prior authorization is required.

February 2024

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: Bariatric Surgery in Adolescents (ages 12-18, who may not yet have completed bone growth) is considered **medically necessary** according to similar weight-based criteria used for adults. **Bariatric Surgery**	May 1, 2024	Commercial	Prior authorization is still required for surgical services.

		Selection Criteria clarified to include: The individual has a BMI >30kg/m2 and has type 2 diabetes. **One anastomosis gastric bypass** added under investigational bariatric surgical procedures for the treatment of class III (BMI >40 kg/m^2 or >35 kg/m^2 with any of the comorbidities listed) obesity in adults who have failed weight loss by conservative measures.			

NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Trans-cutaneous Electrical Nerve Stimulation	003	**Policy clarified.** Added new policy statement to clarify that TENS is investigational for both prevention and treatment of migraine headache. Other policy statements unchanged.	February 1, 2024	Commercial	No action required.

PLASTIC SURGERY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Treatment of Varicose Veins/Venous Insufficiency	238	**Policy revised** to include the following medically necessary statement under *Symptomatic Varicose Tributaries:* Treatments of the tributary veins are considered medically necessary if saphenous reflux is not present or already successfully eliminated, the veins are > than 4 mm in diameter and if the individual remains symptomatic	May 1, 2024	Commercial	Prior authorization is still required.

		after a six-week trial of conservative therapy.			
Suction Lipectomy for Lipedema	043	**New medical policy** describing ongoing medically necessary indications. Medically necessary criteria will be added. Related policies: ▪ MP 068 Plastic Surgery ▪ MP 037 Surgical and Debulking Treatments for Lymphedema	May 1, 2024	Commercial Medicare	Prior authorization is still required.

Carelon Clinical Appropriateness Guidelines

Genetic Testing Guidelines

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

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
Hereditary Cancer		
Hereditary Cancer	**Genetic Counseling** Counseling is strongly recommended prior to hereditary cancer screening that involves genetic testing and should include **ALL** of the following components: • Interpretation of family and medical histories to provide a risk assessment for disease occurrence or recurrence • Education about inheritance, 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: o Limitations of the testing used o A negative result does not indicate heritable risk is zero or low o Identification of inconclusive results called variants of uncertain significance is possible. o Modifications to genetic variants' pathogenicity interpretations	June 30 2024

	can occur and patients may be recontacted with reclassified results in the future *Note: Post-test counseling should be performed for any diagnostic genetic test result.* **Explanation of change:** Clarification	
Hereditary Cancer	**Serrated polyposis syndrome (SPS)** Genetic testing for serrated polyposis syndrome (SPS) is considered not medically necessary for any indication. **Explanation of change:** Clarification on exclusion statement that previously appeared in the rationale for Hamartomatous polyposis syndromes. Now appears as its own section.	June 30 2024
Hereditary Cancer	**Hereditary mixed polyposis syndrome (GREM1-associated mixed polyposis)** Genetic testing for hereditary mixed polyposis syndrome, to include the GREM1 variant OR any other genes, is considered not medically necessary for any indication. **Explanation of change:** Clarification on exclusion statement that previously appeared in the rationale for Hamartomatous polyposis syndromes. Now appears as its own section.	June 30 2024
Hereditary Cancer	**Li-Fraumeni syndrome** Testing for pathogenic or likely pathogenic variants of TP53 is considered medically necessary for individuals at risk based on ANY of the following (per the Chompret criteria, updated in 2015): • Breast cancer diagnosed at age 30 or younger • Breast cancer diagnosed at age 45 or younger and EITHER of the following: ○ At least one first- or second-degree relative with a Li-Fraumeni syndrome spectrum tumor other than breast diagnosed before age 56 ○ At least one first- or second-degree relative with multiple primary cancers at any age • Personal history of a Li-Fraumeni syndrome spectrum tumor other than breast cancer (soft tissue sarcoma, osteosarcoma, CNS tumor) diagnosed at age 45 or younger and EITHER of the following: ○ At least one first- or second-degree relative with a Li-Fraumeni syndrome spectrum tumor before age 56 ○ At least one first- or second-degree relative with multiple primary cancers at any age • Personal history of multiple tumors (other than multiple tumors of the breast), of which two belong to the Li-Fraumeni syndrome spectrum AND at least one was diagnosed at age 45 or younger • Personal history of adrenocortical carcinoma, choroid plexus carcinoma, or embryonal anaplastic rhabdomyosarcoma • Patient who has had a pathogenic or likely pathogenic variant of TP53 identified on tumor genomic testing • Individuals with at least one first-, second-, or third-degree relative with a known TP53 variant **Explanation of change:** Expand indication to include individuals with at least one first-, second-, or third-degree relative with a known TP53 variant.	June 30 2024
Hereditary Cancer	**Hereditary breast, ovarian, and pancreatic cancer (HBOP)** **BRCA1 and BRCA2**	June 30 2024

	Germline genetic testing for known familial pathogenic variants of BRCA1 or BRCA2 is considered medically necessary in the following scenarios: • Any first-, second-, or third-degree relative who has a known BRCA1 or BRCA2 pathogenic variant, where the results will influence reproductive decision-making or decision-making about cancer screening Germline genetic testing panels (see multi-gene panel testing*) that include BRCA1 and BRCA2 are considered medically necessary to aid in current systematic therapy and surgical decision-making in the following scenarios: • Personal history of cancer in individuals assigned female sex at birth with ANY of the following: ○ Epithelial ovarian cancer ○ Pancreatic adenocarcinoma ○ Breast cancer and ANY of the following: ▪ Diagnosis at age 50 years or younger ▪ Triple negative breast cancer ▪ Multiple primary breast cancers (synchronous or metachronous) ▪ Lobular breast cancer concomitant with personal or family history of hereditary diffuse gastric cancer ▪ Ashkenazi Jewish ethnicity ▪ At least one first- or second-degree relative with epithelial ovarian cancer ▪ At least one first-degree relative with metastatic prostate cancer or high risk localized prostate cancer ▪ Two or more first- or second-degree relatives on the same side of the family with breast cancer ▪ At least one first- or second-degree relative with breast cancer diagnosed at age 50 years or younger ▪ At least one first- or second-degree male relative with breast cancer ▪ Two or more first- or second-degree relatives on the same side of the family with pancreatic adenocarcinoma ▪ At least one first- or second-degree relative with bilateral breast cancer or two breast primaries • Personal history of breast or pancreatic cancer in individuals assigned male sex at birth • Individuals assigned female sex at birth with ANY of the following risk profiles: ○ Inherited cancer susceptibility as determined by a validated BRCA1 or BRCA2 mutation assessment tool, including any of the following tools: Ontario Family History Assessment Tool; Manchester Scoring System; Referral Screening Tool; Pedigree Assessment Tool; 7-Question Family History Screening Tool; International Breast Cancer Intervention Study Instrument [Tyrer-Cuzick]; or BRCAPRO [brief version] ○ At least one first-degree relative with breast cancer diagnosed at age 50 years and younger ○ At least one first- or second-degree relative with epithelial ovarian, fallopian tube, or primary peritoneal cancer	

	○ At least one first-degree relative with multiple primary breast cancers (metachronous or synchronous) ○ At least one male first- or second-degree relative with breast cancer ○ Two or more first- or second-degree relatives on the same side of the family with breast cancer, one of whom was diagnosed at age 50 years and younger ○ Two or more first- or second-degree relatives on the same side of the family with breast cancer or prostate cancer with Gleason grade group 2 or higher ○ Three or more first- or second-degree relatives on the same side of the family with breast cancer ○ Ashkenazi Jewish descent AND at least one first-degree relative with breast cancer ○ Ashkenazi Jewish descent AND two or more second-degree relatives on the same side of the family with breast or epithelial ovarian cancer • Individuals with at least two first-degree relatives with pancreatic cancer • Individuals with at least one first- or second-degree relative with epithelial ovarian cancer • Confirmatory testing of persons with positive BRCA1/BRCA2 variants on 23andMe Personal Genome Service (PGS) Genetic Health Risk Report or other commercial entities demonstrating genetic susceptibility based on findings in high penetrance genes related to breast, ovarian, or pancreatic cancer • Note: A positive BRCA1/BRCA2 pathogenic variant identified by 23andMe PGS (or similar commercial direct-to-consumer test) in any individual or first-degree relative requires diagnostic confirmation to be considered. • Focused confirmatory testing for germline genomic analysis demonstrating genetic susceptibility based on specific findings of pathogenic variants found the context of somatic testing for malignancy related to genes (noted in Tables 1, 2, and 3) associated with breast, ovarian, or pancreatic cancer • Confirmatory testing for germline genomic analysis demonstrating genetic susceptibility based on pathogenic variants found related to breast, ovarian, or pancreatic cancer (noted in Tables 1, 2, and 3) when the findings are discovered in the context of IRB-approved clinical research in which the individual being tested has consented to be performed • Current candidates for poly (ADP-ribose) polymerase (PARP) therapy if found to have pathogenic variants in BRCA1 or BRCA2 • Diagnosis of Li-Fraumeni syndrome or Cowden syndrome (PTEN Hamartoma tumor syndrome) with or without a personal history of cancer **Explanation of change:** Expansive for females at birth with multiple primary breast cancers (synchronous or metachronous). Expansive for females at birth with lobular breast cancer concomitant with personal or family history of hereditary diffuse gastric cancer. Expansive for females at birth with breast cancer and at least one first-degree relative with metastatic prostate cancer or high risk localized prostate cancer. Expansive for females at birth with two or more first- or second-degree relatives on the same side of the family with breast cancer or prostate cancer with Gleason grade group 2 or higher. Expansive for individuals with at least one first- or second-degree relative with epithelial ovarian cancer. Expansive for individuals who	

<table>
<tr><td></td><td>would like confirmatory testing of genetic susceptibility to breast, ovarian, or pancreatic cancer demonstrated on somatic tumor testing and/or discovered as part of an IRB-approved clinical research study. Also, several clarification edits.</td><td></td></tr>
<tr><td>Hereditary Cancer</td><td>Hereditary breast, ovarian, and pancreatic cancer (HBOP) Multi-Gene Panel Testing
Germline genetic testing which includes additional pathogenic variants related to breast, ovarian, or pancreatic cancer (see Tables 1, 2, and 3, respectively, for details) is considered medically necessary when ALL of the following criteria are met:
• Panels are targeted to the personal and family history of the individual
• Genes included in the panel have known pathological variants associated with significantly increased risk for breast and/or associated cancers along with established management implications
• Genes included in the panel are associated with clear treatment and or surveillance options
Note: Individuals meeting the criteria for single gene testing who tested negative with previous limited testing sometime in the past (e.g., single gene and/or absent deletion duplication analysis) may be considered for multi-gene panel testing in this scenario. This does not imply that single gene testing is currently necessary before proceeding to multi-gene testing.

Table 1. Genetic testing for genes associated with elevated risk of breast carcinoma
<table><tr><th>Gene – Breast Carcinoma</th><th>Cancer / Syndrome</th></tr><tr><td>ATM</td><td>Breast, Ovarian, Pancreatic</td></tr><tr><td>BARD1</td><td>Breast</td></tr><tr><td>BRCA1 and BRCA2</td><td>Breast, Ovarian, Pancreatic</td></tr><tr><td>CDH1</td><td>Hereditary diffuse gastric cancer, Breast</td></tr><tr><td>CHEK2</td><td>Breast</td></tr><tr><td>PALB2</td><td>Breast (male and female), Ovarian, Pancreatic</td></tr><tr><td>PTEN</td><td>PTEN hamartoma tumor syndrome, Breast</td></tr><tr><td>RAD51C, RAD51D</td><td>Breast, Ovarian</td></tr><tr><td>STK11</td><td>Peutz-Jeghers syndrome, Breast, Pancreatic</td></tr><tr><td>TP53</td><td>Li-Fraumeni syndrome, Breast, Pancreatic</td></tr></table>
Table 2. Genetic testing for genes associated with elevated risk of epithelial ovarian cancer
<table><tr><th>Gene – Epithelial Ovarian Cancer</th><th>Cancer / Syndrome</th></tr><tr><td>ATM</td><td>Breast, Ovarian, Pancreatic</td></tr><tr><td>BRCA1 and BRCA2</td><td>Breast, Ovarian, Pancreatic</td></tr><tr><td>BRIP1</td><td>Ovarian</td></tr><tr><td>MLH1, MSH2, MSH6, PMS2, and EPCAM</td><td>Ovarian, Pancreatic</td></tr><tr><td>PALB2</td><td>Breast (male and female), Ovarian, Pancreatic</td></tr><tr><td>RAD51C, RAD51D</td><td>Breast, Ovarian</td></tr></table>
Table 3. Genetic testing for genes associated with elevated risk of pancreatic adenocarcinoma
<table><tr><th>Gene – Pancreatic Adenocarcinoma</th><th>Cancer / Syndrome</th></tr><tr><td>ATM</td><td>Pancreatic</td></tr><tr><td>BRCA1 and BRCA2</td><td>Breast, Ovarian, Pancreatic</td></tr><tr><td>CDK2NA</td><td>Pancreatic</td></tr><tr><td>MLH1, MSH2, MSH6, PMS2, and EPCAM</td><td>Ovarian, Pancreatic</td></tr><tr><td>PALB2</td><td>Breast (male and female), Ovarian, Pancreatic</td></tr><tr><td>STK11</td><td>Peutz-Jeghers syndrome, Breast, Pancreatic</td></tr><tr><td>TP53</td><td>Li-Fraumeni syndrome, Breast, Pancreatic</td></tr></table></td><td>June 30 2024</td></tr>
</table>

	Explanation of change: Expand multi-gene panel testing to include ovarian and pancreatic cancer. Expansive regarding the gene lists which now include the following: BARD1, RAD51C, and RAD51D for breast carcinoma; ATM, BRCA1, BRCA2, BRIP1, MLH1, MSH2, MSH6, PMS2, EPCAM, PALB2, RAD51C, and RAD51D for epithelial ovarian cancer; and ATM, BRCA1, BRCA2, CDK2NA, MLH1, MSH2, MSH6, PMS2, EPCAM, PALB2, STK11, and TP53 for pancreatic adenocarcinoma) as detailed in revised/additional tables.	
Hereditary Cancer	**Melanoma** Testing for CDKN2A and/or BAP1 pathogenic variants are considered medically necessary for persons at risk for familial melanoma, familial atypical multiple mole melanoma-pancreatic cancer syndromes, or familial atypical multiple mole melanoma syndrome (FAMMM) as defined by ANY of the following diagnostic criteria: • Personal history of three (3) or more melanomas • Personal history of melanoma and pancreatic cancer (exocrine-type) • Personal history of melanoma and a personal or family history in two or more first-degree relatives of mesothelioma or clear cell renal carcinoma or basal cell carcinoma (BAP-1 associated cancers) • Personal history of melanoma and astrocytoma • Three or more first- or second-degree relatives with melanoma or pancreatic cancer • Personal history of invasive cutaneous melanoma who have a first-degree relative diagnosed with pancreatic cancer (exocrine-type) • Both melanoma and astrocytoma in two or more first-degree relatives **Explanation of change:** Expansive, to align with NCCN. Also, clarification changes.	June 30 2024
Hereditary Cancer	**Nevoid basal cell carcinoma syndrome** Focused genetic testing that may include testing for PTCH variants (including associated downstream variants, such as SMO and SUFU) are considered medically necessary for persons at risk for nevoid basal cell carcinoma syndrome based on the following diagnostic criteria. The individual must meet ANY of the following: TWO (2) major criteria, ONE major criterion AND two minor criteria, OR THREE (3) minor criteria. [No changes to Major criteria and Minor criteria] **Explanation of change:** Clarified downstream variants.	June 30 2024
Hereditary Cancer	**Kidney cancer** Germline genetic testing for a single gene OR a targeted panel is considered medically necessary for hereditary kidney cancer syndromes in individuals with a personal history of ANY of the following: • Renal cell carcinoma diagnosed at age 46 or younger • Bilateral or multifocal renal tumors • At least one first- or second-degree relative with renal cell carcinoma **Explanation of change:** Clarification only. Table (not shown here) added to the Rationale with examples of variants, prevalence, and renal cell carcinoma risk listed by condition.	June 30 2024

Hereditary Cancer	**Prostate cancer** (Also see Lynch syndrome and HBOP) Germline genetic testing of a focused set of 20 or fewer specific genes which may include HOXB13, BRCA2, BRCA1, CHEK2, PALB2, ATM, MLH1, MSH2, MSH6, PMS2, and EPCAM to inform assessment of hereditary risk of prostate cancer is considered medically necessary for individuals with a history of ANY of the following: • Personal history of ANY of the following: ○ Metastatic, locally advanced, or high/very-high risk localized prostate cancer ○ Intermediate risk prostate cancer with intraductal or cribriform histology or Ashkenazi descent by family history ○ Prostate cancer diagnosed before age 60 AND at least one first-degree relative with prostate cancer diagnosed before age 60 ○ One or more pathogenic variants found by tumor somatic testing of ANY of the following genes: ▪ BRCA2, BRCA1, CHEK2, ATM, PALB2, MLH1, MSH2, MSH6, PMS2, or EPCAM ○ Low or intermediate risk localized prostate cancer concomitant with a personal history of breast, pancreatic, melanoma, intestinal (colorectal or small bowel), or upper tract urothelial cancer(s) • Family history of ANY of the following: ○ Two or more first-degree relatives with prostate cancer ○ One or more first-degree relatives with prostate cancer diagnosed before age 60 or who died of prostate cancer **Explanation of change:** Expansive regarding the gene list (which now adds up to 20 genes and includes PALB2, MLH1, MSH2, MSH6, PMS2, and EPCAM), and the gene list for those pathogenic variants found by somatic tumor testing. Expansive for circumstances where intermediate risk and where low- or intermediate-risk localized prostate cancer are now considered medically necessary. Clarifications and reorganization.	June 30 2024
Carrier Screening in the Reproductive Setting (Previously in the Prenatal Setting and Preimplantation Genetic Testing		
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplan-tation Genetic Testing**	**Genetic counseling** The approach chosen for any reproductive carrier screening program should involve shared decision-making between the patient and the clinician. Counseling is encouraged prior to any reproductive carrier screening that involves genetic testing and should include ALL of the following components: • Interpretation of family and medical histories to provide a risk assessment for disease occurrence or recurrence • Education about inheritance patterns, disease severity of conditions being screened for, and the potential need for prenatal diagnosis for confirmation of an affected fetus should the couple be found to be both carriers of the same condition • 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 for carrier screening should include the following details: ○ Positive/carrier results are common and will not usually have an impact on one's own health ○ Carrier screening of the individual's partner is	June 30 2024

	recommended if the individual is found to be a carrier of an autosomal recessive condition ○ Carrier screening may rarely uncover incidental findings, such as a possible diagnosis and/or personal health risks ○ A negative result reduces, but does not eliminate carrier risk Note: Post-test counseling should be performed for any at-risk individuals/couples. **Explanation of change:** Clarifications	
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplantation Genetic Testing**	**Standard carrier screening** Standard screening for cystic fibrosis (CFTR testing) and spinal muscular atrophy (SMN1 testing) using accepted gene variant sets is considered medically necessary for all pregnant individuals or an individual considering pregnancy and their reproductive partners. 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 (CBC, hemoglobin electrophoresis and/or HBA1/HBA2 and HBB gene analysis) are available for interpretation: • All pregnant individuals • An individual considering pregnancy AND their reproductive partner **Explanation of change:** Expansive to include standard hemoglobinopathy screening for all pregnant individuals or an individual considering pregnancy. Clarifications.	June 30 2024
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplantation Genetic Testing**	**Condition specific carrier testing based on family history** Targeted 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 the genetic condition being evaluated • The reproductive partner of the individual being tested has a pathogenic variant in the gene associated with the condition being evaluated **Explanation of change:** Clarifications	June 30 2024
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplantation Genetic Testing**	**Expanded carrier screening*** Expanded carrier screening (i.e., multigene testing) 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, Mediterranean, Southeast Asian, among others) known to be at increased risk for certain conditions, other than cystic fibrosis, spinal muscular atrophy, and hemoglobinopathies (e.g., conditions that have a carrier frequency of at least 1 in 100 in that ancestry) ○ The individual and their reproductive partner are known or suspected to be consanguineous ○ 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	June 30 2024

	• The genes included on the panel are consistent with the above bullet point reason for testing • The genetic disorders being evaluated have gene disease clinical validity AND pathogenic variants in the genes are associated with significant morbidity and/or mortality in affected individuals • The test has sufficiently high sensitivity and specificity to guide clinical decision making • Alternate biochemical or other clinical tests are not available, have provided an indeterminate result, or are less accurate than genetic testing • 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: Expanded carrier screening should target genes that are associated with family history and ancestry. Additionally, genes included in the panel should be shown to impact patient management and health outcomes. **Explanation of change:** Clarifications	
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplantation Genetic Testing**	**Preimplantation genetic testing** Criteria moved to Genetic Testing for Inherited Conditions **Explanation of change**: Moved preimplantation testing criteria to Genetic Testing for Inherited Conditions; removed from title of Carrier Screening guidelines.	June 30 2024
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplantation Genetic Testing**	**Exclusions** The following tests and clinical scenarios are considered not medically necessary: • Carrier screening for conditions known to have adult-onset including, but not limited to, genetic testing for breast cancer (e.g., BRCA gene testing) • Cell-free DNA screening for single gene disorders, microdeletions, or other indications not otherwise specified • Variants with high allele frequencies and low penetrance of a phenotype (e.g., methylene tetrahydrofolate reductase variants) • Whole exome or whole genome assays for the purpose of carrier screening • Molecular screening for conditions where nonmolecular screening techniques can be used (e.g., hereditary hemochromatosis has low penetrance when molecular variants are identified) **Explanation of change:** Clarifications	June 30 2024
Genetic Testing for Inherited Conditions		
Genetic Testing for Inherited Conditions	**Genetic counseling** Counseling is strongly recommended prior to genetic testing and should include ALL of the following components: • Interpretation of family and medical histories to provide a risk assessment for disease occurrence or recurrence	June 30 2024

	• Education about inheritance, 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 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 diagnostic genetic test result. **Explanation of change:** Clarifications. This is nearly the same Genetic Counseling verbiage used in Hereditary Cancer Testing.	
Genetic Testing for Inherited Conditions	**Genetic testing for inherited conditions** Genetic testing is considered medically necessary for an individual when ALL the following criteria are met: • The individual is either suspected to have a known genetic condition based on clinical presentation or the individual may be pre-symptomatic but at significant risk based on family history* • The genetic disorder being evaluated has clearly defined gene(s) and pathogenic variants associated with it and the associated test has high sensitivity and specificity to guide clinical decision making • The genetic testing has established analytical and clinical validity and is performed in an appropriately accredited and certified laboratory • Alternate, biochemical, or other clinical tests are not available, provide an indeterminate result or are less effective than genetic testing • The natural history of the disease is associated with significant morbidity and or mortality in affected individuals • Knowledge of the pathogenic variant(s) is expected to directly impact clinical management (predictive, diagnostic, surveillance, therapeutic, or reproductive) of the individual *Family history of the condition(s) being evaluated is present in first-, second- or third-degree relatives as applicable to the inheritance pattern of the condition (i.e., autosomal dominant, autosomal recessive, X-linked). This may also include family history of a known pathogenic variant with or without expression of the condition being evaluated. Confirmatory genetic testing is considered medically necessary for an individual identified to have a pathological variant based on FDA-approved direct-to-consumer genetic testing ONLY if ALL the criteria above have been met. **Testing may be performed only once per lifetime for a given condition.** **Explanation of change:** Clarifications	June 30 2024
Genetic Testing for Inherited	**Multi-gene panel testing for inherited conditions** Panel testing may be considered when ALL general and condition-specific criteria are met AND ALL of the following criteria are met:	June 30 2024

Conditions	• Any multi-gene panel should be as focused as reasonably possible taking into account the prevalence of each gene and the clinical utility of identifying the presence or absence of a pathogenic variant in each gene • Each gene included in the panel must have evidence to show their association with the condition AND pathogenic variants in each gene could affect clinical management • Testing for the more probable genes should be performed before gene panel testing where clinically appropriate **Explanation of change:** Clarifications	
Genetic Testing for Inherited Conditions	**Cardiac conditions** **Post-mortem testing after sudden cardiac death** After sudden cardiac death, genetic testing for pathogenic variants associated with cardiac channelopathies are considered medically necessary when BOTH of the following criteria are met: • The decedent is < 50 years old • The cause of sudden cardiac death remains unexplained despite the clinical history and autopsy, toxicology, and cardiac pathology findings **Explanation of change**: Clarification (only change ALL to BOTH)	June 30 2024
Genetic Testing for Inherited Conditions	**Neurological conditions** Genetic testing for pathogenic variants associated with inherited neurological conditions may be medically necessary when the general requirements OR multi-gene panel criteria listed above are met. Genetic testing for screening or diagnosis of ANY of the following common categories of neurological conditions is considered not medically necessary: • Alzheimer's dementia • Frontotemporal dementias (i.e., Parkinsons's disease, Pick disease, and others) • Motor neuron diseases (such as amyotrophic lateral sclerosis) Note: This guideline does not address testing to guide selection of FDA-approved therapeutics with specific indications based on biomarker test results. Please refer to the Pharmacogenomic Testing guidelines. **Explanation of change:** Clarifications include adding a table summarizing major categories of inherited neurologic conditions.	June 30 2024
Genetic Testing for Inherited Conditions	**Thrombophilia testing** Thrombophilia testing for common pathogenic variants associated with Factor V Leiden or the prothrombin (Factor II) gene G20210A is considered medically necessary to inform anticoagulation decision-making when ANY of the following criteria are met: • Individuals with venous thromboembolism (VTE) at age 50 or under in association with unprovoking/weakly provoking factors, recurrent VTE, or strong family history of VTE • Individuals with VTE involving the cerebral or splanchnic veins • An individual contemplating pregnancy who has a first-degree relative with VTE and a known hereditary thrombophilia • An individual with an unprovoked VTE and low bleeding risk is planning to stop anticoagulation, test for thrombophilia if test results would change this decision • An individual contemplating estrogen use with a first-degree relative with VTE and a known hereditary thrombophilia test for that thrombophilia	June 30 2024

	Not Medically Necessary: MTHFR-gene variant testing for hereditary thrombophilia risk assessment is considered not medically necessary. **Explanation of change**: Clarification only. NMN statement for MTHFR-gene variant testing was in the rationale but should be part of the main body.	
Genetic Testing for Inherited Conditions	**Preimplantation genetic testing** Preimplantation genetic testing is considered medically necessary when the embryo(s) is at increased risk of a recognized inherited condition based on ALL of the following: • The medical inherited condition and gene variants being evaluated would result in significant morbidity and/or mortality • The condition is known to result from a single gene (PGT-M) abnormality, or from structural changes of a gamete provider, preimplantation genetic testing for structural rearrangements (PGT-SR) • Gamete providers meet ONE of the following criteria: ○ Both gamete providers are known carriers of the same autosomal recessive condition ○ One partner is a known carrier of an autosomal recessive disorder, and the couple have previously produced offspring affected by that condition ○ At least one gamete provider is a known carrier of an autosomal dominant or sex-linked condition ○ One gamete provider is at greater than or equal to 25% risk to be a carrier of an autosomal dominant single gene condition or an X-linked condition based on family history and is requesting non-disclosure testing (e.g., Huntington's disease; X-linked adrenoleukodystrophy) ○ At least one gamete provider is a carrier of a balanced structural chromosome abnormality ○ At least one gamete provider is an anonymous reproductive donor with unknown/unavailable carrier status when the other gamete provider is a known carrier Preimplantation Genetic Testing for aneuploidy (PGT-A) is considered medically necessary when there is a clear heritable indication. Heritable indications include: • X-linked recessive conditions • Sex-limited conditions **Explanation of change**: Expansive for gamete providers in certain scenarios. Clarifications changes. Clarification about PGT-A medical necessity (previous guideline was silent). Moved preimplantation testing criteria from Carrier Screening guidelines.	June 30 2024
Genetic Testing for Inherited Conditions	**Not Medically Necessary:** PGT is considered not medically necessary for ALL the following indications: • PGT-A in the absence of heritable risk • Testing solely to determine if an embryo is a carrier of an autosomal recessive condition • Multifactorial conditions • Polygenic risk scores/disorders (PGT-P) • Variants of unknown significance • Gender selection in the absence of sex-linked or sex-limited risk • Nonmedical traits such as physical characteristics like height and eye color, etc.	June 30 2024

	Explanation of change: Clarification on what is not medically necessary. The previous guideline was silent.	
Genetic Testing for Inherited Conditions	**Biomarker testing for rejection in solid organ transplantation** Use of AlloMap gene-expression profiling for monitoring adolescent and adult patients post cardiac transplantation who are considered low risk for graft rejection is medically necessary when ALL of the following criteria are met: • The individual is at least 15 years old and at least 6 months post cardiac transplantation • The individual is clinically stable and does not have signs or symptoms of congestive heart failure • The individual does not have signs or symptoms of graft rejection or require acute treatment for rejection • Testing is not more frequent than the following: ○ Every 3 months between month 6 and month 24 after transplantation ○ Every 6 months between month 24 and month 60 after transplantation ○ Testing does not extend beyond 60 months after transplantation **Not Medically Necessary:** Donor-derived cell free DNA testing (to include, although not limited to, AlloSure and Prospera) for use as a biomarker for diagnosis and/or monitoring of cardiac organ transplant rejection is considered not medically necessary. Genetic testing (including donor-derived cell free DNA testing, gene expression profiling, or microRNA testing) for use as a biomarker for diagnosis and/or monitoring of kidney or other (non-cardiac, to include lung) organ transplant rejection is considered not medically necessary. **Explanation of change:** Clarification only – listed in rationale but does not specifically call out "cardiac" in criterion.	June 30 2024

January 2024

ANESTHESIOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment Noncovered Services	400	**Policy clarified** to add the following regional anesthetic blocks to the non-covered list: ▪ QLB (Quadratus lumborum) block for abdominal, pelvic and hip surgery ▪ ESP (Erector spinae plane) block for thoracic, abdominal, pelvic and hip surgery ▪ IPACK (Infiltration between popliteal	December 8, 2023	Commercial Medicare	No action required.

		artery and posterior capsule) block following total knee arthroplasty or arthroscopically assisted ACL reconstruction.			

GASTROENTEROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis	451	**Policy revised.** New investigational policy statement added for use in gastroparesis. Previous policy statement unchanged.	April 1, 2024	Commercial Medicare	No action required.
Fecal Microbiota Transplantation (FMT)	682	**Policy revised.** Medically necessary policy statement added for commercially available FDA-approved FMT products, Rebyota and Vowst.	April 1, 2024	Commercial Medicare	No action required.

HEMATOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Omidubicel as Adjunct Treatment for Hematologic Malignancies	028	**Policy revised.** Medically necessary statement added. Prior authorization is required on effective date noted.	April 1, 2024	Commercial Medicare	Prior authorization is required.

NEUROSURGERY ORTHOPEDICS

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Bone Morphogenetic Protein	097	**Policy revised.** Prior authorization will no longer be required on effective date noted.	April 1, 2024	Commercial Medicare	Prior authorization is not required.

OBSTETRICS GYNECOLOGY GENETIC TESTING

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis	711	**Policy revised** to include coverage for 0352U and 0353U bacterial vaginosis and vaginitis and chlamydia trachomatis and Neisseria gonorrhoeae codes when policy criteria are met.	April 1, 2024	Commercial Medicare	No action required.
Carelon Genetic Testing Management Program CPT and HCPCS Codes	957	CPT code 81420 removed. This code is out of scope from the Carelon Program. PA is no longer required through Carelon. 81420 Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	February 1, 2024	Commercial	Prior authorization is not required through Carelon.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
CNS Stimulants and Psychothera-peutic Agents	019	**Policy revised.** Criteria for Armodafinil and Modafinil were updated.	April 1, 2024	Commercial	Prior authorization is still required.
Asthma and Chronic Obstructive Pulmonary Disease Medication Management	011	**Policy criteria revised.** FDA approved indications/diagnoses will be required for Breztri and Trelegy.	April 1, 2024	Commercial	Prior authorization is still required.
Medicare Advantage Part B Step Therapy	020	**Policy revised** to remove Step Therapy requirement for	December 31, 2023	Medicare	No action required.

		treprostinil and Remodulin.			

RADIOLOGY IMAGING

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Carelon Oncologic Imaging CPT, HCPCS and Diagnoses Codes	929	HCPCS code A9608 added. Prior authorization is required through Carelon on effective date. A9608 Flotufolastat f18, diagnostic, 1 millicurie	January 1, 2024	Commercial	Prior authorization is required through Carelon.

December 2023

ANESTHESIOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Monitored Anesthesia Care (MAC)	154	**Policy clarified.** American Society of Anesthesiology (ASA) Physical Status Classification examples added. The list of risk factors or significant medical conditions guidelines clarified. **Policy clarified** to include 2023 UpToDate® information on screening for colorectal cancer in patients with a family history of colorectal cancer or advanced polyp. Clarified coding information. **Enforcement update** Covered diagnoses codes list added to the policy. New diagnoses-to-CPT codes edit to be implemented on January 1, 2024.	January 1, 2024	Commercial Medicare	Prior authorization **is still not required.**

CARDIOLOGY

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

GASTROENTEROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Fecal Calprotectin Testing	329	**Policy revised.** Medically necessary indications described. 83993 Calprotectin, fecal	March 1, 2024	Commercial Medicare	No action required.
Medical Technology Assessment Investigational (Non-Covered) Services List	400	**Policy revised.** CPT code 83631 Lactoferrin, fecal; quantitative removed from the non-covered list.	March 1, 2024	Commercial Medicare	No action required.
Monitored Anesthesia Care (MAC)	154	**Policy clarified.** American Society of Anesthesiology (ASA) Physical Status Classification examples added. The list of risk factors or significant medical conditions guidelines clarified. **Policy clarified** to	January 1, 2024	Commercial Medicare	Prior authorization **is still not required.**

		include 2023 UpToDate® information on screening for colorectal cancer in patients with a family history of colorectal cancer or advanced polyp. Clarified coding information. **Enforcement update** Covered diagnoses codes list added to the policy. New diagnoses-to-CPT codes edit to be implemented on January 1, 2024.			

NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Remote Electrical Neuromodu-lation for Migraines	145	**Policy revised.** Remote electrical neuromodulation for prevention of migraine is considered investigational.	March 1, 2024	Commercial Medicare	No action required.

OBSTETRICS GYNECOLOGY

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

		58573			

ORTHOPEDICS

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Suture Button Suspension-plasty Fixation System for Thumb Carpometa-carpal Osteoarthritis	031	**New medical policy** describing investigational indications. Suture button suspensionplasty for thumb carpometacarpal joint osteoarthritis is considered investigational.	March 1, 2024	Commercial Medicare	No action required.
Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions	374	**This policy will be retired.** InterQual criteria will be used to determine coverage for this procedure.	March 1, 2024	Commercial Medicare	Prior authorization is still required. Submit prior authorization requests using Authorization Manager.

PHARMACY

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

		▪ Adalimumab-fkjp ▪ Hyrimoz (Cordavis product) **Non-Covered Specialty and Non-Preferred in Policy** ▪ Amjevita **(after 4/1/2024)** ▪ Cyltezo ▪ Hyrimoz ▪ Idacio ▪ Yuflyma **REMICADE** **Effective 4/1/2024**, we will be moving Remicade to a non-covered position. We will continue to cover Inflectra and Avsola as preferred alternatives with Renflexis and Infliximab as non-preferred alternatives to Remicade.			

PRIMARY CARE MEDICINE; LABORATORY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Vitamin D Assay Testing	746	**Reminder** Frequency claim edits will be added to reinforce the policy. Claims will process according to the policy and reduce the number of claims that need post-payment review. **Repeat Testing** Once a patient is identified as vitamin D deficient, further testing may be medically necessary to ensure there has been adequate replacement. If the patient is not vitamin D deficient, repeat testing is not medically necessary.	January 1, 2024	Commercial	No action required.

Laboratory Testing Investigational Services	165	**Policy clarified.** Ongoing investigational codes 0376U, 0384U, 0385U, were transferred from MP #400 Non-covered services list to MP #165. These tests are considered investigational. There are no assigned specific codes: • Prometheus® IBD sgi Diagnostic® • Prometheus® Crohn's Prognostic • know error® Codes 0368U, 0380U, 0405U, 0410U are managed by Carelon. Prior authorization is required from Carelon.	December 1, 2023	Commercial Medicare	No action required.

RADIOLOGY

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

VASCULAR SURGERY

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

Carelon Clinical Appropriateness Guidelines

Genetic Testing Guidelines

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

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

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

Cell-free DNA Testing for Cancer

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer	**Individuals with locally advanced (stage IIIb), recurrent, or metastatic non-small cell lung cancer** Liquid (ctDNA) based testing is considered **medically necessary** for individuals with pathologically confirmed locally advanced (stage IIIb), recurrent, or metastatic non-small cell lung cancer (NSCLC), and **ALL** of the following criteria are met: • There is insufficient tumor tissue available for NGS-based somatic profiling or for whom tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition • No prior NGS-based somatic profiling test has previously been performed for this pathological diagnosis of NSCLC • The test is being used to provide genetic information related to the current set of actionable mutations recognized by ASCO guidelines to inform management at diagnosis or treatment progression on or after chemotherapy or immunotherapy **Explanation of change:** Clarification **Individuals with metastatic breast cancer who may benefit from PIK3CA or ESR1-targeted therapy** Liquid (ctDNA) based testing, to include PIK3CA and/or ESR1 somatic tumor testing, is considered **medically necessary** to identify individuals who may benefit from the use of alpelisib or elacestrant, respectively (or other FDA-approved targeted agent) when **ALL** of the following criteria are met: • The individual is either an adult man OR postmenopausal woman • The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for an applicable FDA-approved targeted agent • The individual has not had prior testing for the targeted gene of interest in the metastatic setting • There is insufficient tumor tissue available for NGS-based somatic profiling or tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition **Explanation of change:** Clarification **Individuals with metastatic adenocarcinoma of the prostate who may benefit from a PARP inhibitor or PD-1 inhibitor** Liquid (ctDNA) based testing is considered **medically necessary** for individuals with metastatic adenocarcinoma when **ALL** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the prostate • The individual has not had prior NGS testing in the metastatic setting • The individual is a candidate for **ONE** of the following therapies: • FDA-approved PARP inhibitor (olaparib, rucaparib, or other approved PARP inhibitor)	March 17, 2024

	• FDA-approved PD-1 inhibitor (pembrolizumab, or other approved checkpoint inhibitor) • There is insufficient tumor tissue available for NGS-based somatic profiling or tissue biopsy is unsafe or considered infeasible due to the individual's clinical condition **Explanation of change:** Clarification	

Somatic Tumor Testing

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

Carelon Guideline	Policy Change Summary	Effective Date
Umbrella Criteria – same for solid tumors and hematologic malignancies		
Somatic Genomic Testing (Tumor Biomarker Testing)	Somatic genomic testing is considered **medically necessary** in individuals with cancer when **ALL** of the following criteria are met: • The genomic testing has established analytical and clinical validity (i.e., FDA-approved test, when available) and is performed in an appropriately certified laboratory • The genetic test has established clinical utility such that a positive or negative result will meaningfully impact the clinical management (predictive, diagnostic, prognostic, or therapeutic) of the individual and will likely result in improvement in net health outcomes (i.e., the health benefits of the interventions outweigh any medical or psychological harmful effects of the testing intervention) • When there are genomic biomarker-linked therapies approved by the U.S. Food and Drug Administration (FDA) for the individual's specific cancer scenario and such therapies are being considered in the near term • When considering a treatment for which there are specific genomic biomarker-based contraindications or exclusions related therapeutic decisions being considered in the near term ○ Clinical decision making incorporates the known or predicted impact of a specific genomic alteration on protein expression or function and published clinical data on the efficacy of targeting that genomic alteration with a particular agent **Explanation of change:** Clarification	March 17, 2024
Somatic Testing of Solid Tumors **Metastatic or Advanced Cancer (Tumor Agnostic Testing)**		
Tumor agnostic testing for patients with advanced solid tumors	Multi-gene panel testing is considered **medically necessary when ALL** of the following are true: • The individual has a metastatic or advanced solid tumor and adequate performance status for cancer treatment • A genomic biomarker-linked therapy has been approved by the FDA for their cancer clinical scenario, or there are established genomic biomarker-based treatment contraindications or exclusions • There are no existing indications for the planned therapy such that its use does not depend on the results of genetic testing (i.e., immune checkpoint inhibitor indications) • There are no satisfactory tumor-specific standard therapies	March 17, 2024

	available • Testing falls into **ANY** of the following categories: ○ Mismatch-repair (MMR) deficiency ▪ MLH1, MSH2, MSH6, PMS2 or EPCAM genes by PCR or NGS testing ▪ Microsatellite testing (MSI) and/or dMMR testing ▪ MLH-1 promoter methylation and/or BRAF V600E mutation testing with nuclear expression loss of MLH1 and PMS2 by immunohistochemistry ○ Tumor mutational burden (TMB) testing ○ NTRK and RET fusion testing ○ BRAF V600E mutation testing **Explanation of change:** Clarification. Removed "FDA-approved" under MMR deficiency (covered by the Umbrella Criteria now).	
Cancer-specific Criteria		
Bladder Cancer (Urothelial Carcinoma, including the Upper Tract)	Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing for FGFR variants is considered **medically necessary** for individuals with urothelial tumors of the bladder or upper urinary tract when **ALL** of the following criteria are met: • The individual has biopsy-proven urothelial malignancy • The urothelial malignancy is locally advanced or metastatic • The individual is a potential candidate for an FDA-approved targeted therapy prescribed on the basis of the FGFR test result • The individual has not had prior FGFR testing in the metastatic setting Tissue-based somatic tumor testing for microsatellite instability (MSI testing, to include dMMR IHC) is considered **medically necessary** for individuals with muscle-invasive urothelial tumors of the upper urinary tract. *Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details.* **Explanation of change:** Restrictive (number of genes), Clarifications	March 17, 2024
Breast Cancer	**Localized breast cancer** Gene expression profiling is considered **medically necessary** for individuals with localized breast cancer using Oncotype DX, MammaPrint, EndoPredict, Prosigna Breast Cancer Prognostic Gene Signature Assay, or the Breast Cancer Index when **ALL** of the following criteria are met: • [No change to criteria] Gene expression profiling with the Oncotype DX or MammaPrint is considered **medically necessary** for postmenopausal females and adult males (referring to the sex assigned at birth) with 1 to 3 positive axillary lymph nodes (pN1a, pN1b or pN1c) when **ALL** of the following criteria are met: • Surgery has been performed and a full pathological	March 17, 2024

	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 • Chemotherapy is being considered by the individual and their provider • No other breast cancer gene expression profiling assay has been conducted for this tumor (including testing on any metastatic foci or on other sites when the tumor is multifocal) **Explanation of change:** Clarification to include all individuals in this clinical setting referring to the sex assigned at birth (females or males) **Metastatic breast cancer** Testing for somatic pathogenic variants of PIK3CA is considered **medically necessary** for postmenopausal females and adult males when **ALL** of the following criteria are met: • The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for alpelisib or another FDA-approved PIK3CA-targeted agent • The individual has not had prior testing for PIK3CA in the metastatic setting Testing for somatic pathogenic variants of ESR1 is considered **medically necessary** for postmenopausal females and adult males when **ALL** of the following criteria are met: • The individual has ER-positive and HER-negative metastatic breast cancer • The individual is a candidate for treatment for elacestrant per the FDA label • The individual has not had prior testing for ESR1 in the metastatic setting Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the **Tumor Agnostic Testing** guideline for details. **Explanation of change:** Clarification	
Cholangiocarcinoma (Biliary Tract Cancers)	Tissue-based somatic tumor testing for pathogenic variants in individuals with cholangiocarcinoma is considered **medically necessary** when **ALL** of the following criteria are met: • The individual has biopsy-proven cholangiocarcinoma • The cholangiocarcinoma is locally advanced, unresectable, or metastatic • The panel testing is inclusive of the following pathogenic variants: IDH1, FGFR, and BRAF • The individual is a potential candidate for FDA-approved targeted therapy prescribed on the basis of the panel test results • The individual has not had prior somatic tumor testing in the	March 17, 2024

	metastatic setting Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details. **Explanation of change:** Clarifications. Added FDA-approved to therapy.	
Colorectal Cancer	**Localized colorectal cancer** Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered **medically necessary** for individuals with localized (stage II-III) colorectal cancer when **BOTH** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the colon or rectum • Includes **ANY** or **ALL** of the following, with no prior testing ○ MSI testing and/or dMMR IHC testing ○ BRAF V600E variant (RAS variants may also be part of some targeted panels) ○ MLH-1 promoter methylation and/or BRAF V600E mutation testing with nuclear expression loss of MLH1 and PMS2 by immunohistochemistry **Explanation of change:** Expansive (RAS variant add), Restrictive (number of genes), Clarification **Metastatic colorectal cancer** Targeted (i.e., 50 or less genes) tissue-based somatic tumor testing is considered **medically necessary** for individuals with metastatic colorectal cancer and may be performed on the primary tumor or a metastatic site when **ALL** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the colon or rectum • Assessment includes **ANY or ALL** of the following: ○ MSI testing and/or dMMR IHC testing ○ Extended RAS testing (KRAS and NRAS variants) ○ BRAF V600E variant ○ HER2 testing ○ MLH-1 promoter methylation and/or BRAF V600E mutation testing with nuclear expression loss of MLH1 and PMS2 by immunohistochemistry • There has been no prior testing *Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details.* **Explanation of change**: Restrictive (number of genes), Clarification	March 17, 2024

Endometrial Carcinoma, Advanced	Tissue-based somatic tumor testing is considered **medically necessary** for individuals with advanced endometrial carcinoma and may be performed on the primary tumor or a metastatic site when **ALL** of the following criteria are met: • The individual has biopsy-proven endometrial carcinoma • Assessment includes the following, as applicable: ○ MSI-H and/or Dmmr mismatch repair testing ○ MLH-1 promoter methylation testing with IHC nuclear expression loss of MLH1 and PMS2 • There has been no prior testing *Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details. Additionally, for MLH1 germline testing for Lynch Syndrome, please refer to the Hereditary Cancer Testing guideline.* **Explanation of change**: Clarification. Removed "FDA-approved" (covered by the Umbrella Criteria now).	March 17, 2024
Melanoma	**Diagnostic and prognostic testing in melanoma** Gene expression profiling of suspected or established cutaneous, mucosal, or uveal melanoma for diagnosis or prognostication is considered **not medically necessary** **Explanation of change**: Clarification **Somatic tumor testing in advanced melanoma** Tissue-based somatic tumor testing for **BRAF V600E** pathogenic variant by validated IHC, PCR, or NGS methods for individuals with resectable or unresectable stage III or stage IV cutaneous melanoma or high-risk stage IIC cutaneous melanoma is considered **medically necessary** when **BOTH** of the following criteria are met: • The individual has biopsy-proven cutaneous malignant melanoma • Prior testing has not been performed Tissue-based somatic tumor testing for individuals with resectable or unresectable stage III or stage IV melanoma or high-risk stage IIC melanoma that is **BRAF V600E wild-type or mucosal melanoma** is considered **medically necessary** when **ALL** of the following criteria are met: • The individual has biopsy-proven malignant melanoma • Prior testing has not been performed • Testing includes **ANY** or **ALL** of the following: ○ KIT variant testing ○ NRAS variant testing ○ Additional BRAF variant testing Testing of individuals with **metastatic uveal melanoma for HLA-A*0201** using is considered **medically necessary** when **ALL** of the following criteria are met: • The individual has biopsy-proven uveal melanoma and evidence of metastatic disease • Prior testing for HLA-A*0201 has not been performed • The individual is a candidate for treatment with tebentafusp	March 17, 2024

	** Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details.* **Explanation of change**: Clarifications. BRAF mutations are rare in uveal melanoma and not relevant in treating mucosal melanoma, so the BRAF testing is appropriately focused on cutaneous melanoma. To accommodate additional testing for mucosal melanoma (particularly KIT testing), mucosal melanoma is explicitly added here because those patients will generally not have been tested for BRAF V600E already.	
Ovarian Cancer (Epithelial)	Targeted (i.e., 50 or less genes) tissue-based somatic testing for pathogenic variants of BRCA1, BRCA2, and to determine HRD status in individuals with recurrent epithelial ovarian cancer is considered **medically necessary** when **ALL** of the following criteria are met: • The individual has biopsy-proven epithelial ovarian cancer • The individual is a candidate for treatment with an FDA-approved PARP inhibitor • The individual has not had prior testing for these genes in the metastatic setting Germline testing for pathogenic variants is considered **medically necessary** for all individuals with epithelial ovarian carcinoma. *See Hereditary Cancer Testing guideline for further details.* *Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details.* **Explanation of change:** Restrictive (number of genes), Clarification. Removed "FDA-approved complementary diagnostic test" (covered by the Umbrella Criteria now).	March 17, 2024
Pancreatic Adenocarcino-ma	Germline testing for pathogenic variants is considered **medically necessary** for all individuals with pancreatic adenocarcinoma. *See Hereditary Cancer Testing guideline for further details.* Tissue-based somatic tumor testing for microsatellite instability (MSI testing, to include dMMR IHC) is considered **medically necessary** for individuals with locally advanced or metastatic pancreatic adenocarcinoma. *Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details.*	March 17, 2024

	Explanation of change: Clarification	
Prostate Cancer	**Localized prostate cancer** Gene expression profiling and genomic biomarker tests as a technique for prostate cancer screening, detection, and management are considered **not medically necessary** for all indications. **Metastatic prostate cancer** Tissue-based NGS panel testing is considered **medically necessary** to identify pathogenic variants in individuals with metastatic prostate cancer when **ALL** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the prostate • The individual is a candidate for **ONE** of the following therapies: ○ FDA-approved PARP inhibitor (olaparib, rucaparib, or another PARP inhibitor approved for use in this setting) ○ FDA-approved PD-1 inhibitor (pembrolizumab or another checkpoint inhibitor approved for use in this setting) • The NGS panel includes BRCA2, BRCA1, and ATM, and may also include other genes encoding molecules involved in homologous recombination DNA damage repair (DDR) such as PALB2, FANCA, RAD51D, CHEK1/2, BARD1, and CDK12, among others • The individual has not had prior NGS testing in the metastatic setting Tissue-based somatic tumor testing for microsatellite instability (MSI testing, to include dMMR IHC) is considered **medically necessary** for individuals with locally advanced or metastatic prostate cancer. Germline testing for pathogenic variants is considered **medically necessary f**or all individuals with metastatic prostate adenocarcinoma. See Hereditary Cancer Testing guideline for further details. *Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details.* **Explanation of change**: Clarification	March 17, 2024
Thyroid Cancer	**Testing of indeterminate thyroid nodules (ITN)** Use of next-generation gene expression classifier testing from fine needle aspirate sampling of a thyroid nodule is considered **medically necessary** when **ALL** of the following criteria are met: • There has been no prior testing of the same thyroid nodule • Initial cytopathology is reported as **ANY** of the following (Bethesda III or IV) categories: ○ Atypia of undetermined significance (AUS) ○ Follicular lesion of undetermined significance (FLUS) ○ Suspicious for follicular neoplasm (SFN) ○ Follicular neoplasm (FN)	March 17, 2024

	• The ITN is <4 cm in size AND does NOT have findings highly suspicious for malignancy on ultrasound (American Thyroid Association high suspicion pattern or American College of Radiology TIRADS 5) • **ONE** of the following gene expression classifiers will be used: ○ ThyGeNEXT/ThyraMIR multiplatform test ○ ThyroSeq Genomic Classifier **Explanation of change:** Restrictive (removed Afirma – no longer offer standalone assay that is considered medically necessary, and incorporated radiographic findings)	
Unknown Primary Site Cancer	Gene expression profiling and somatic genetic testing for individuals to predict the site of tumor origin (i.e., non-agnostic tissue testing) of cancer of unknown primary are considered **not medically necessary**. *Note: Tumor agnostic genetic testing indications may also apply depending on the clinical scenario (e.g., there are no satisfactory tumor-specific standard therapies available, there are no indications for planned therapy that would apply independent of the results of genetic testing [such as immune checkpoint inhibitor indications], and progression of disease). See the Tumor Agnostic Testing guideline for details* . **Explanation of change:** Clarification	March 17, 2024
Somatic Testing of Hematologic Malignancies Cancer-specific criteria		
Acute Lymphocytic Leukemia	Tissue- (**OR** bone marrow-) based (**OR** alternatively, peripheral blood if morphologically detectable circulating blasts) somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for children and adults with acute lymphoblastic leukemia (ALL) to establish the diagnosis or to identify actionable therapeutic targets when **ANY** of the following criteria are met: • A multi-gene panel contains, at a minimum, the following genes: ABL1, ABL2, CRLF2, CSF1R, FLT3, IL7R, JAK1, JAK2, JAK3, PDGFRB, SH2B3, TP53, and IKZF1 Chromosomal analyses of bone marrow specimens (or alternatively, peripheral blood if morphologically detectable circulating blasts), which may also include FISH testing, to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for children and adults with ALL. The use of NGS testing on bone marrow specimen is considered **medically necessary** to detect or quantify measurable/minimal residual disease (MRD) in children or adults with ALL. BCR-ABL kinase domain point mutation analysis is considered **medically necessary** in the evaluation of individuals with BCR-ABL (Philadelphia chromosome) positive ALL to evaluate treated individuals who manifest suboptimal response to initial tyrosine kinase inhibitor therapy or loss of response to tyrosine kinase inhibitor therapy. PCR testing for BCR-ABL1 quantification on bone marrow specimen	March 17, 2024

	is considered **medically necessary** in the monitoring of Philadelphia chromosome-positive ALL. **Explanation of change**: Expansive (specimen-type), Restrictive (number of genes, specimen-type, MRD and BCR-ABL1 monitoring), Clarification	
Acute Myelogenous Leukemia	Tissue-based (OR alternatively, peripheral blood if morphologically detectable circulating blasts) somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for individuals with acute myelogenous leukemia (AML) to establish the diagnosis and to identify actionable therapeutic targets when **ANY** of the following criteria are met: • A multi-gene panel contains, at a minimum, the following genes: FLT3, IDH1, IDH2, NPM1 CEBPA, DDX41, TP53; ASXL1, BCOR, EZH2, RUNX1, SF3B1, SRSF2, STAG2, U2AF1, ZRSR2 Chromosomal analyses of preferred bone marrow specimens, which may also include FISH testing, to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for individuals with AML **Explanation of change**: Expansive (specimen-type), Restrictive (number of genes), Clarification	March 17, 2024
Chronic Myeloid Leukemia	Bone marrow tissue-based **OR** peripheral blood somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for establishing the diagnosis of suspected chronic myelogenous leukemia (CML) when the following criterion is met: • PCR or FISH testing includes the evaluation of the BCR-ABL1 fusion gene BCR-ABL kinase domain point mutation analysis is considered **medically necessary** in the monitoring of CML in **ANY** of the following circumstances: • Evaluation of individuals with CML to evaluate treated individuals who manifest suboptimal response to tyrosine kinase inhibitor therapy indicated by: ○ Lack of a partial hematologic or cytogenetic response at 3 months or greater after treatment onset ○ Less than a complete hematologic and cytogenetic response at 12 months ○ Disease progression to accelerated or blast phase Chromosomal analyses of bone marrow specimens to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for individuals with CML. PCR testing for BCR-ABL1 quantification is considered **medically necessary** for response assessment every 3 months during active treatment and every 6 weeks in the first year after treatment discontinuation. **Explanation of change:** Restrictive (number of genes), format change to emphasize only one type of specimen for testing	March 17, 2024

Multiple Myeloma	**Gene expression profile tests** Gene expression profile tests for diagnostic evaluation, risk stratification, or management of multiple myeloma are **considered not medically necessary.** **Chromosomal analyses of bone marrow specimens** Chromosomal analyses of bone marrow specimens to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for individuals with multiple myeloma. The use of NGS testing of tumor DNA from bone marrow specimens to detect or quantify minimal residual disease (MRD) in individuals with myeloma is considered **medically necessary** under **EITHER** of the following circumstances: • MRD testing used prior to initiating new treatment intended to induce myeloma remission • MRD testing used to assess depth of response after a cycle of treatment intended to induce myeloma remission **Explanation of change:** Restrictive (specimen-type, MRD)	March 17, 2024
Myeloproliferative Neoplasms	Bone marrow tissue-based **OR** peripheral blood somatic genetic testing (i.e., 50 or less genes) is considered **medically necessary** for establishing the diagnosis of suspected myeloproliferative neoplasms (MPN) (e.g., essential thrombocytosis, polycythemia vera, chronic neutrophilic leukemia, and primary myelofibrosis) when **BOTH** of the following criteria are met: • PCR, FISH, or NGS testing is targeting applicable JAK2, CALR, CSF3R, and MPL genes • **ONE** of the following clinical scenarios: ○ Hemoglobin ≥16.5 g/dL in male and hemoglobin ≥16.0 g/dL in female ○ Hematocrit greater than 49% in male and hematocrit greater than 48% in female ○ Platelet count ≥450 X 109/L ○ Leukocytosis (white blood cell) ≥11 X 109/L • **Explanation of change:** Restrictive (number of genes), format change to emphasize only one type of specimen for testing	March 17, 2024
Myelodysplastic Syndrome	Somatic testing (i.e., 50 or less genes) of bone marrow tissue **OR** peripheral blood is considered **medically necessary** for individuals with clinically diagnosed or suspected myelodysplastic syndrome when **ANY** of the following criteria are met: • Testing is for the purpose of establishing the diagnosis or to identify actionable therapeutic targets • A targeted multi-gene panel contains, at a minimum, the following genes: ASXL1, DNMT3A, EZH2, NRAS, RUNX1, SF3B1, SRSF2, STAG2, TET2, TP53, U2AF1, ZRSR2 Chromosomal analyses of preferred bone marrow specimens to detect and characterize clonal chromosomal abnormalities that have important diagnostic, prognostic, and therapeutic implications are considered **medically necessary** for individuals with myelodysplastic syndrome.	March 17, 2024

	Explanation of change: Expansive (specimen-type), Restrictive (number of genes), Clarification	

Radiology Guidelines

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

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
	Cardiac CT	
Cardiomyo-pathy	**Cardiomyopathy** Cardiac CT is considered medically necessary in **ANY** of the following scenarios: • Evaluation of patients with suspected arrhythmogenic right ventricular dysplasia (ARVD) who have **ANY** of the following: o Severe right ventricular dysfunction on another cardiac imaging study ○ Precordial T wave inversion not associated with RBBB ○ First-degree relative with established ARVD or unexplained sudden cardiac death at age younger than 35 years ○ Ventricular tachycardia or frequent PVCs (> 500 in 24 hours or > 30 per hour) [no change to remaining criteria] **Explanation of change:** Added specificity to establish the basis for the suspicion of ARVD. This change aligns with Cardiac MRI guidelines.	April 14, 2024

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
	Cancer Screening	
Breast cancer screening	**Breast cancer screening** • Individuals known to have **ANY** of the following established	April 14, 2024

	genetic mutations: ○ ATM ○ BARD1 ○ CDH1 ○ CHEK2 ○ NF-1 ○ PALB2 ○ PTEN ○ RAD51C or RAD51D ○ STK11 (Peutz-Jeghers syndrome) **Explanation of change:** Addition of high-risk genetic mutations (NCCN alignment citing absolute risk of 20% or greater)	
Lung cancer screening	**Lung cancer screening** Annual low-dose CT is indicated when **ALL** of the following criteria are met: • Age equal to or greater than 50 and less than or equal to 80 • 20 or greater pack-year history* of cigarette smoking (current smoker, or quit date within the past 15 years), or established asbestosis-related lung disease **Explanation of change:** Clarification of asbestos-related lung disease as risk factor independent of smoking, aligned with original intent.	April 14, 2024
Pancreatic cancer screening	**Pancreatic cancer screening** Annual CT or MRI (preferred) Abdomen is indicated as an alternative to endoscopic ultrasound in **ANY** of the following scenarios: • Peutz-Jeghers syndrome (LKB1/STK11 mutations), starting at age 30-35 or 10 years earlier than youngest affected relative • Familial Atypical Multiple Melanoma and Mole syndrome (FAMMM; CDKN2A, p16 mutation), starting at age 40 or 10 years earlier than youngest affected relative • BRCA1, BRCA2, PALB2, ATM, EPCAM, TP53, or MLH1/MSH2/MSH6 (Lynch syndrome) gene mutation and at least one first- or second- degree relative* with pancreatic cancer, starting at age 50 or 10 years earlier than the youngest affected relative • Hereditary pancreatitis gene mutation (PRSS1 or SPINK1) with personal or family history of recurrent acute pancreatitis, starting at age 40 or 20 years after the initial onset of pancreatitis • Family history of pancreatic cancer, starting at age 50 or 10 years earlier than the youngest affected relative in **EITHER** of the following: ○ At least two first-degree relatives* ○ At least three first- and/or second-degree relatives* **Relative(s) with exocrine pancreatic cancer, on the same side of the family as the gene mutation or history of pancreatic cancer* **Explanation of change** Alignment with NCCN recommended parameters; changes are overall expansive, except for: ▪ Older start age (from 45 to 50) for certain genes (ATM, BRCA1, BRCA2, MLH1, MSH2, MSH6, EPCAM, PALB2, TP53) ▪ Family history alone (relative requirement)	April 14, 2024
Breast Cancer		
Breast Cancer	**CT chest, CT abdomen and pelvis**	April 14,

	Diagnostic Workup: Indicated for stage IIIA-IV or clinically suspected metastatic disease **Explanation of change:** Added diagnostic workup allowance when metastatic disease is clinically suspected at presentation. **MRI Breast** Surveillance: Indicated annually for a personal history of breast cancer after breast conserving therapy or unilateral mastectomy in ANY of the following scenarios: • Meets criteria for MRI breast screening • In patients with dense** breasts after breast conservation surgery and radiation therapy • Breast cancer diagnosis before age 50 **Explanation of change:** Addition/clarification of surveillance scenarios aligned with NCCN/ACR considerations **FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Radiation planning for treatment of locoregional recurrence • Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease • Evaluation of elevated LFTs or rising tumor markers when standard imaging has not clearly identified a site of recurrence or progression • Restaging/treatment response when bone is the only site of measurable disease in the chest, abdomen, and pelvis **Explanation of change:** Added allowance for RT planning locoregional recurrence (e.g. confirmation of regional nodal involvement). 18F-fluoroestradiol (18F-FES) PET/CT Suspected Cancer: Not indicated Diagnostic Workup: Not indicated Management: Not indicated Surveillance: Not indicated **Explanation of change:** Uncertain net benefit; low-level evidence, insufficient data on outcomes.	2024
Cervical Cancer		
Cervical Cancer	**FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease • Following radiation or chemoradiation when performed at least 12 weeks following completion of therapy • Signs or symptoms concerning for recurrent or metastatic disease **Explanation of change:** Update for follow-up of disease treated with either adjuvant RT or chemoradiation (NCCN alignment).	April 14, 2024
Hepatocellular and Biliary Tract Cancers		
Hepatocellular and Biliary Tract Cancers	**FDG-PET/CT** Diagnostic Workup and Diagnosis: Indicated when standard imaging cannot be performed or is nondiagnostic regarding the extent of disease **Management:** Indicated when standard imaging cannot be	April 14, 2024

	performed or is nondiagnostic for recurrent or progressive disease **Explanation of change:** Removal of routine preop PET/CT for biliary tract cancers (NCCN alignment) Added management allowance when standard imaging cannot be done or is nondiagnostic (NCCN "consider" for equivocal finding)	
	Lung Cancer – Non-Small Cell	
Lung Cancer – Non-Small Cell	**FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Radiation planning for preoperative or definitive treatment • Evaluation following induction or neoadjuvant therapy, to determine eligibility for resection • Assessment of response to definitive chemoradiation when performed at least 12 weeks following therapy • Standard imaging cannot be performed, or is nondiagnostic for recurrent or progressive disease • Surveillance CT Chest demonstrates recurrence **Explanation of change:** Addition of management allowance when recurrence demonstrated by surveillance imaging (NCCN alignment)	April 14, 2024
	Lung Cancer – Small Cell	
Lung Cancer – Small Cell	**FDG-PET/CT** Diagnostic Workup: Indicated prior to definitive therapy when standard imaging is nondiagnostic for extent of disease **Explanation of change:** Clarification of initial staging allowance (NCCN alignment)	April 14, 2024
	Lymphoma – Non-Hodgkin and Leukemia	
Lymphoma – Non-Hodgkin and Leukemia	Lymphoma – Non-Hodgkin: Intermediate and high grade non-Hodgkin lymphoma **FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Radiation planning prior to definitive or consolidative treatment • Interim restaging following 2-4 cycles of treatment • Evaluation at completion of therapy • Evaluation of suspected recurrence or progression of disease based on standard imaging or objective signs/symptoms **Explanation of change:** NCCN alignment for interim restaging (allowed for DLBCL stage I-IV with or without bulky disease)	April 14, 2024
	Melanoma	
Melanoma	**MRI Abdomen** Diagnostic Workup: See "Suspected or Known Metastases" Management: See "Suspected or Known Metastases" Surveillance: Indicated for uveal melanoma when liver ultrasound cannot be performed or nondiagnostic **Explanation of change:** Addition of surveillance option with MRI abdomen for liver metastases.	April 14, 2024
	Prostate Cancer	
Prostate Cancer	**18F Fluciclovine PET/CT or 11C Choline PET/CT** **68GaProstate-specific membrane antigen (PSMA) PET/CT**	April 14, 2024

	or 18F-DCFPyL (piflufolastat or Pylarify) PET/CT Diagnostic Workup and Diagnosis: Indicated for unfavorable intermediate or high risk disease with equivocal or nondiagnostic conventional imaging,2 when confirmation may inform decisions about prostatectomy and/or radiation therapy Management: Indicated in **EITHER** of the following scenarios: • When **ALL** of the following criteria are met: ○ Original clinical stage T1-T3 and NX or N0 treated with prostatectomy and/or radiation therapy, with biochemically recurrent/persistent disease1 ○ Negative or nondiagnostic conventional imaging2 (within 60 days) if PSA ≥ 10 ng/ml ○ Patient is a candidate for curative intent salvage therapy3 ○ PET/CT has not been performed within the past 3 months • Evaluation of metastatic castrate-resistant disease for radioligand therapy when previously treated with taxane-based chemotherapy AND ANY of the following: ○ androgen-receptor pathway inhibitors ○ Abiaterone ○ Apalutamide ○ Enzalutamide ○ Darolutamide **Explanation of change:** Addition of diagnostic workup/initial staging indication. Specification of androgen-receptor pathway inhibitor treatment in alignment with Carelon Radiation Oncology guidelines	
Sarcomas of Bone/Soft Tissue		
Sarcomas of Bone/Soft Tissue	**Bone Sarcoma, Soft Tissue Sarcoma** **FDG-PET/CT** Management: Indicated in **EITHER** of the following scenarios: • Following completion of neoadjuvant chemotherapy • Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease **Explanation of change:** Added allowance when standard imaging nondiagnostic or contraindicated (bone/soft tissue sarcoma).	April 14, 2024

Brain Imaging

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Neurodegenerative Conditions		
Movement disorders (Adult only)	**Movement disorders (Adult only)** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • For pre-procedural evaluation when MR-guided focused ultrasound (MRgFUS) is planned for essential tremor • For perioperative evaluation related to placement of a deep brain stimulator • For initial evaluation of the following movement disorders, to exclude an underlying structural lesion:	April 14, 2024

	○ Hemifacial spasm ○ Huntington's disease ○ Multiple system atrophy ○ Parkinson's disease with atypical features ○ Progressive supranuclear palsy ○ Secondary dystonia ○ Other focal or lateralizing movement disorder, such as hemiballismus, athetosis, or chorea *Note: Imaging is generally not indicated for evaluation of typical Parkinson's disease or primary dystonia. Other than pre-procedural imaging for MRgFUS, imaging is generally not indicated for essential tremor.* **IMAGING STUDY** • CT brain • MRI brain (preferred) – for indications above other than essential tremor **Explanation of change** Added indication for CT head for assessment of skull density prior to MRgFUS for essential tremor	
Trauma		
Trauma	**Trauma** ***PEDIATRIC*** Advanced imaging is considered medically necessary in the diagnosis and management of head trauma in **EITHER** of the following scenarios: • Acute trauma when **ANY** of the following risk factors are present: ○ Altered mental status ○ Change in behavior ○ Vomiting ○ Loss of consciousness ○ History of high-risk motor vehicle accident or other mechanism of injury ○ Scalp hematoma when younger than age 2 years ○ Evidence of basilar skull fracture ○ Non-accidental injury • Non-acute trauma in **EITHER** of the following scenarios: ○ Focal neurological signs or symptoms that are new, progressive, or unexplained by CT performed for acute trauma ○ Progressive nonfocal neurologic signs or symptoms (including postconcussive syndrome) refractory to therapy ○ A follow-up study 3-6 weeks after head trauma in patients age 6 years or younger, when the neurologic exam is stable or inconclusive **Explanation of change:** Added a 3-6 week follow up study in patients age 6 or younger with stable or inconclusive exam, due to difficulty in accurately assessing for changes in neurologic status	April 14, 2024
Tumor or Neoplasm		
Acoustic neuroma	**Acoustic neuroma** *Also see indication for hearing loss.* *Also see Head and Neck Imaging guidelines.*	April 14, 2024

	Advanced imaging is considered medically necessary for management and surveillance of known acoustic neuroma in patients with neurofibromatosis type 2 or in **ANY** of the following scenarios: Management • Signs, symptoms or imaging findings suggestive of recurrence or progression Surveillance • Following conservative treatment ("watch and wait") or incomplete resection (including proton beam therapy or stereotactic radiosurgery) annually for 5 years and then every 5 years thereafter • A follow up study following gross total resection within the first year after surgery, and follow-up studies at 2 years, 5 years, and 10 years after surgery **Explanation of change:** Added long-term follow-up intervals based on specialty society guidelines	
Signs and Symptoms		
	Headache Advanced imaging is considered medically necessary to evaluate for an intracranial lesion as a secondary cause of headaches in **ANY** of the following scenarios: • Thunderclap or sentinel headache, sudden onset and severe (worst headache of life), reaching maximal intensity within minutes • Headache triggered by or occurring primarily in association with exertion or Valsalva including cough, exercise, or sexual activity • Positional or orthostatic headache • New onset of headache over age 50 • Change in headache pattern • Abnormal neurological exam • Unexplained and unexpected increase in frequency and/or severity of headaches **Explanation of change:** Modified language for clarity based on Operations feedback	April 14, 2024

Head and Neck Imaging

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Tumor/Soft Tissue Mass		
Acoustic neuroma	**Acoustic neuroma** Advanced imaging is considered medically necessary for management and surveillance of known acoustic neuroma in patients with neurofibromatosis type 2 or in **ANY** of the following scenarios: Management • Symptoms or imaging findings suggestive of recurrence or progression Surveillance • Following conservative treatment ("watch and wait") or	April 14, 2024

	incomplete resection (including proton beam therapy or stereotactic radiosurgery) annually for 5 years and then every 5 years thereafter • A follow up study following gross total resection within the first year after surgery, and follow-up studies at 2 years, 5 years, and 10 years after surgery **Explanation of change:** Added long-term follow-up intervals based on specialty society guidelines	
Signs and Symptoms		
Localized facial pain (including trigeminal neuralgia)	**Localized facial pain (including trigeminal neuralgia)** Advanced imaging is considered medically necessary for evaluation when localized facial pain is persistent and unexplained. **IMAGING STUDY** • CT orbit, sella, or posterior fossa and outer, middle, or inner ear • MRI orbit, face, and neck (soft tissue) **Explanation of change:** Added MRI orbit/face/neck for this indication based on ACR criteria; some facilities use MRI face rather than brain for this condition	April 14, 2024

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Perioperative or periprocedural evaluation, not otherwise specified		
Navigational bronchoscopy planning for pulmonary mass or nodule	**Navigational bronchoscopy planning for pulmonary mass or nodule** Advanced imaging is considered medically necessary for use in navigational bronchoscopy when being done for **EITHER** of the following reasons: • Planning of a biopsy to be done using navigational bronchoscopy, when neither percutaneous biopsy nor traditional bronchoscopy can be performed. • Placement of fiducial markers for radiation therapy or localization for surgical resection of a pulmonary mass **IMAGING STUDY** • CT chest **Explanation of change:** Added indication for CT chest to be used for planning of biopsy or placement of fiducial markers using navigational bronchoscopy	April 14, 2024

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE

Hepatobiliary Indications		
Biliary tract dilatation or obstruction	**Biliary tract dilatation or obstruction** Advanced imaging is considered **medically necessary** for diagnosis and management in **ANY** of the following scenarios: • Unexplained biliary tract dilation • Biochemical evidence of biliary obstruction following nondiagnostic ultrasound • Annual evaluation of patients with Caroli disease or Caroli syndrome **Explanation of change:** Added indication for annual surveillance in Caroli disease/syndrome based on a 2022 guideline recommendation	April 14, 2024
Diffuse liver disease	**IMAGING STUDY** Multiparametric MRI (LiverMultiScan) as an alternative to MR elastography for diagnosis and management of advanced hepatic fibrosis/cirrhosis **Explanation of change:** Removed indication for LiverMultiScan in hemochromatosis as there is insufficient evidence that this provides an advantage over standard MRI for this condition	April 14, 2024
Osseous Indications		
Osteomyelitis	**Osteomyelitis** ***ADULT*** Advanced imaging is considered medically necessary following nondiagnostic radiographs. ***PEDIATRIC*** Advanced imaging is considered medically necessary for diagnosis and management **Explanation of change:** Added requirement for initial evaluation with radiographs in adult patients based on ACR appropriateness criteria	April 14, 2024
Septic arthritis	**Septic arthritis** ***ADULT*** Advanced imaging is considered medically necessary following nondiagnostic radiographs. ***PEDIATRIC*** Advanced imaging is considered medically necessary for diagnosis and management. **Explanation of change:** Added requirement for initial radiographs in adult patients based on ACR appropriateness criteria	April 14, 2024
Pancreatic Indications		
Pancreatic mass, indeterminate cystic (IPMN/IPMT)	**Pancreatic mass, indeterminate cystic (IPMN/IPMT)** ***ADULT*** Advanced imaging is considered medically necessary for diagnosis, management, and surveillance in surgical candidates when EUS/FNA has not been performed or is nondiagnostic in **ANY** of the following scenarios: • Initial evaluation of an indeterminate mass identified on ultrasound • Age 80 or greater at the time of diagnosis in **EITHER** of the following scenarios: ○ Every other year for up to 4 years if not increasing in size	April 14, 2024

	○ Every 12 months if enlarging • Cysts less than 1.5 cm in a patient of age less than 80 at the time of diagnosis ○ Age less than 65 at diagnosis: every 12 months for up to 9 years from the time of initial diagnosis ○ Age 65 to 79 at diagnosis: every 24 months for up to 10 years from the time of initial diagnosis, or every 12 months if the lesion has worrisome features (enhancing nodules or peripheral calcification) or if the patient has high risk of pancreatic malignancy • Cysts 1.5 cm or greater in a patient of age less than 80 at the time of diagnosis Every 6-12 months for 2 years then yearly for up to 10 years **Explanation of change:** For enlarging lesions in patients age 80 or greater, increased surveillance frequency to annually and removed endpoint of 4 years.	
Miscellaneous Conditions		
Pelvic floor disorders	**Pelvic floor disorders** Advanced imaging is considered medically necessary for diagnosis and management in **ANY** of the following scenarios: • Functional disorder of the pelvic floor associated with urinary or bowel incontinence • Physical examination findings suspicious for pelvic organ prolapse • Chronic constipation, when anorectal manometry or balloon expulsion tests are nondiagnostic **IMAGING STUDY** • MRI pelvis (Dynamic MRI (MR defecography) technique is preferred[119, 120)] **Explanation of change:** Added indication for MRI (MR defecography preferred) in suspected pelvic organ prolapse based on ACR appropriateness criteria	April 14, 2024
Perioperative evaluation, not otherwise specified		
Transplant-related imaging	**Transplant-related imaging** Advanced imaging is considered medically necessary in the following scenarios: • For living donors, a single pre-transplant evaluation • For patients on the transplant waiting list for liver transplantation, annual surveillance • Single evaluation prior to lung, kidney, or hematopoietic stem cell transplantation • Evaluation of suspected post-transplant complications **Explanation of change:** Added indication for single CT abdomen or abdomen/pelvis prior to lung, kidney, or stem cell transplant to align with CT chest guidelines.	April 14, 2024

Radiation Oncology

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

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

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

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

	dosage is the same with each fraction is a little larger (now 2 Gy) and lower number of fractions.	

Proton Beam Therapy
No changes.

Therapeutic Radiopharmaceuticals
No changes.

Hydrogel Spacer for Prostate Radiotherapy
No changes

November 2023

GENETIC TESTING; OBSTETRICS GYNECOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Carelon Genetic Testing Management Program CPT and HCPCS Codes	957	**Policy revised** to remove CPT 81420. This code is no longer in-scope under the Carelon Genetic Testing Program. PA is no longer required from Carelon or Blue Cross. CPT 81420: Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	February 1, 2024	Commercial	No action required.

HEMATOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Gene Therapies for Hemophilia A or B	168	**New policy** describing medically necessary and investigational indications for Roctavian added. Title updated to include gene therapies	November 1, 2023	Commercial Medicare	Prior authorization is required.

		for Hemophilia A. Hemgenix policy criteria #3 **clarified** to replace "AND" with "OR."			

ORTHOPEDICS; NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty	482	**Policy revised.** Investigational policy statement on Intraosseous Basivertebral Nerve Ablation removed from MP 482. See new MP 485 Intraosseous Basivertebral Nerve Ablation describing medically necessary indications.	February 1, 2024	Commercial Medicare	No action required.
Intraosseous Basivertebral Nerve Ablation	485	**New medical policy** describing medically necessary indications.	February 1, 2024	Commercial Medicare	Prior authorization is required.

TRANSPLANTATION; ENDOCRINOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Islet Transplantation for Chronic Pancreatitis and Donislecel-jujn for Type 1 Diabetes	324	**Policy revised.** Investigational statement added for use of donislecel-jujn in type 1 diabetes. Policy title updated.	February 1, 2024	Commercial	No action required.

October 2023

BEHAVIORAL HEALTH

Neuro-psychological and Psychological Testing	151	Neuropsychological testing criteria transferred from InterQual and clarifications made to	January 1, 2024	Commercial	No action required.

		policy statements. Intent of policy statements unchanged. Policy references updated.			

GASTROENTEROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment Investigational (Non-Covered) Services List	400	**Policy clarified.** Home Breath Test Kits edited to include SIBO (small intestinal bacterial overgrowth) breath test. This is still not a covered service.	September 13, 2023	Commercial Medicare	No action required.

HEMATOLOGY ONCOLOGY; GENETIC TESTING

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical Technology Assessment Investigational (Non-Covered) Services List	400	**Policy clarified.** NavDx DNA Blood Test for detection of HPV-driven cancer removed. Prior authorization is required through Carelon. 0356U Oncology (oropharyngeal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence.	September 13, 2023	Commercial Medicare	No action required.
Omidubicel as Adjunct Treatment for Hematologic Malignancies	028	**New medical policy** describing investigational indications. Omidubicel is considered investigational in individuals with hematologic malignancies planning myeloablative allogenic	January 2024	Commercial Medicare	No action required.

		umbilical cord transplantation.			

OBSTETRICS GYNECOLOGY

Assisted Reproductive Services	086	**Clarifications** made to Intrauterine insemination, IVF evaluation requirements and cryopreservation after IVF cycle sections.	October 1, 2023	Commercial	No action required.

MULTISPECIALTY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Outpatient Prior Authorization Code List for Commercial Plans	072	**Policy clarified/reminder.** Prior authorization requests for services listed in MP 072 are to be submitted using Authorization Manager. Authorization Manager helps streamline the prior authorization request process.	September 2023	Commercial	Refer to our Authorization Manager page for tips, guides, and video demonstrations.
Medical Technology Assessment Investigational (Non-Covered) Services List	400	**Policy clarified.** Nidra Device using TOMAC (tonic motor activation therapy) for restless leg syndrome added.	October 1, 2023	Commercial Medicare	No action required.

ORTHOPEDICS NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Orthopedic Applications of Stem Cell Therapy (Including Allograft and Bone Substitute Products Used with Autologous Bone Marrow)	254	**Policy clarified.** Table 1. Demineralized Bone Matrix Products Cleared by FDA added. Policy statements unchanged.	September 6, 2023	Commercial Medicare	No action required.

Bone Morphogenetic Protein	097	**Policy clarified.** Regulatory Status section added. Table 1 clarified. Policy statements unchanged.	9/6/2023	Commercial Medicare	PA is still required.
Percutaneous and Subcutaneous Tibial Nerve Stimulation	583	**Policy revised.** Investigational policy statement added for subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system for all indications, including individuals with non-neurogenic urinary dysfunction including overactive bladder. Title updated.	January 1, 2024	Commercial	No action required.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Multiple Sclerosis, Prior Auth and Step Policy	839	**Policy revised.** Prior authorization will be required for new prescriptions of Kesimpta. The following medications will no longer require step therapy but will require prior authorization to be covered. This applies to new prescriptions for these medications: Avonex, Betaseron, Extavia, Plegridy, Rebif.	January 1, 2024	Commercial	PA is still required.
Entyvio (Vedolizumab) Policy	162	**Policy revised.** Dosing and frequency of use will be required as part of prior authorization for Entyvio in order to be covered under the medical benefit.	January 1, 2024	Commercial	PA is still required.
Nononcologic Uses of Rituximab	123	**Policy revised.** Dosing and frequency of use will be required as part of prior authorization for	January 1, 2024	Commercial	PA is still required.

		the following medications in order for them to be covered under the medical benefit: Riabni, Rituxan, Ruxience, Truxima.			
Soliris, Ultomiris, Myasthenia Gravis, and Neuromyelitis Optica Policy	093	**Policy revised.** Dosing and frequency of use will be required as part of prior authorization for Soliris in order to be covered under the medical benefit.	January 1, 2024	Commercial	PA is still required.
Vascular Endothelial Growth Factor (VEGF) Inhibitors Step Therapy – Medical Benefit	092	**Policy revised.** This policy will be updated to remove Alymsys, MVASI, Vegzelma and Zirabev. This policy is changing to a prior authorization policy and all Step 2 and Step 3 medications under this policy will transition from a step therapy to a prior authorization requirement. Prior authorization will be required for new prescription for any medication under this policy.	January 1, 2024	Commercial	PA is still required.
Injectable Specialty Medication Coverage	071	**Policy revised.** This policy will be updated to include Simponi Aria and Stelara.	January 1, 2024	Commercial	PA is still required.
Bisphos-phonates, Oral	058	This **policy will be retired** on January 1, 2024.	January 1, 2024	Commercial	No action required.
Medication Utilization Management (MED UM) & Pharmacy Prior Authorization	033	**Policy revised.** This medical policy will be updated to include Briumvi and Ocrevus. Prior authorization will be required for new and existing prescriptions to be covered under the medical or pharmacy benefit. Tysabri currently requires prior	January 1, 2024	Commercial	PA is still required.

		authorization under the medical benefit and will require prior authorization under the pharmacy benefit, effective January 1, 2024. Dosing and frequency of use will be required as part of prior authorization for the following medications in order for them to be covered under the medical benefit: Prolia, Tepezza, Xgeva.			
Injectable Asthma Medications	017	**Policy revised.** Dosing and frequency of use will be required as part of prior authorization for Xolair in order to be covered under the medical benefit.	January 1, 2024	Commercial	PA is still required.
Immune Modulating Drugs Policy	004	**Policy revised.** This policy will be updated to reflect the removal of medical benefit coverage for Simponi Aria and Stelara mentioned above. Dosing and frequency of use will be required as part of prior authorization for the following medications: Actemra (non-preferred), Avsola (preferred), Orencia (non-preferred), Inflectra (preferred), Infliximab (non-preferred), Remicade (non-preferred), Renflexis (non-preferred). These medications are covered under the pharmacy benefit, and the medical benefit for providers that signed the medical benefit amendment to buy and bill.	January 1, 2024	Commercial	PA is still required.
Quality Care Cancer	099	**Policy revised.** Riabni will move from	January 1, 2024	Commercial Medicare	PA is still required.

Program (Medical Oncology)		preferred to non-preferred and Truxima will move from non-preferred to preferred for new prescriptions. Prior authorization through Carelon Medical Benefit Management, as part of the Quality Care Cancer Program, will continue to be required.			
Supportive Care Treatments for Patients with Cancer	105	**Policy revised.** Fulphila will move from preferred to non-preferred for new prescriptions.	January 1, 2024	Commercial Medicare	PA is still required.
Medicare Advantage Part B Step Therapy	020	**Policy revised.** ▪ Vabysmo and Susvimo will be added to Step 2 medication. ▪ Treprostinil will be added to Step 1 medication and Remodulin will be added to Step 2 medication. ▪ Truxima will be added to Step 1 medication and Riabni will be added to Step 2 medication. ▪ Infliximab will be added to Step 2 medication. ▪ Prior authorization will be required for members new to therapy; existing users within the past 365 days will be grandfathered.	January 1, 2024	Medicare	Providers will be required to use a Step 1 medication prior to use of a Step 2 medication.

September 2023

BEHAVIORAL HEALTH

POLICY TITLE	POLICY	POLICY CHANGE	EFFECTIVE	PRODUCTS	PROVIDER ACTIONS

	NO.	SUMMARY	DATE	AFFECTED	REQUIRED
Digital Health Technologies Therapies for Attention Deficit /Hyperactivity Disorder	947	**Policy statements clarified** from "Prescription digital therapy is considered investigational for the treatment of attention-deficit/hyperactivity disorder" to "The use of EndeavorRx is considered investigational for all indications including attention-deficit/hyperactivity disorder"; intent unchanged.	September 1, 2023	Commercial Medicare	No action required.

DERMATOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Benign Skin Lesions	707	**Policy criteria revised. Enforcement update** List of covered diagnoses codes added. New diagnoses-to-CPT codes edit to be implemented on January 1, 2024.	January 1, 2024	Commercial	PA is not required.

DURABLE MEDICAL EQUIPMENT

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Manual and Power Operated Wheelchairs	365	**Policy revised** to include coverage for wheelchair accessory, power seat elevation system, any type (HCPCS E2300) for all products.	May 16, 2023	Commercial	Prior authorization **is still required** for Power Operated Wheelchairs.

ENDOCRINOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Continuous or	107	**Prior authorization**	December	Commercial	No action

Intermittent Monitoring of Glucose in Interstitial Fluid and Artificial Pancreas Device Systems		**<u>requirements</u>** • PA is **not required** for type 1 diabetes. PA is **not required** for the following codes A4238; A4239; A9277 for type 1 diabetes. • PA will continue to be **required for type 2 diabetes**. PA is **still required** for the following codes A4238; A4239; A9277 for type 2 diabetes. **<u>Continuous Glucose Monitoring</u>** **Policy revised.** • Medically necessary statement related to type 1 diabetes streamlined to include type 1 diabetes in individuals who can use the device. • Medically necessary statements related to type 2 diabetes expanded to include individuals on any insulin therapy. • Adding coverage for the free style libre device for gestational diabetes. **<u>Artificial Pancreas Device Systems</u>** **Policy revised.** New indication and medically necessary policy statement with criteria added for the artificial pancreas device system with a closed-loop insulin delivery system (bionic pancreas).	1, 2023		required.

MULTISPECIALTY: NOT LIMITED TO GASTROENTEROLOGY | NEUROLOGY | HEMATOLOGY | ENDOCRINOLOGY

POLICY TITLE	POLICY	POLICY CHANGE	EFFECTIVE	PRODUCTS	PROVIDER ACTIONS

	NO.	SUMMARY	DATE	AFFECTED	REQUIRED
Vitamin B12 Testing	061	New medical policy describing medically necessary and investigational indications. **Enforcement update** List of covered diagnoses codes added. Diagnoses-to-CPT codes edit to be implemented on December 1, 2023.	December 1, 2023	Commercial Medicare	PA is not required.

NEUROLOGY | REHABILITATION | ORTHOPEDICS

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy and Restorative Neurostimulation Therapy	172	**Policy revised**. New indication and investigational policy statement added for restorative neurostimulation therapy (Reactiv8). Policy statements for percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy separated out for clarity; intent unchanged. Title changed to reflect new indication.	December 1, 2023	Commercial	No action required.

PLASTIC SURGERY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Plastic Surgery	068	**Hair removal** **Policy revised.** Hair removal, including electrolysis and laser, may be considered medically necessary after treatment of a pilonidal cyst to prevent recurrence.	December 1, 2023	Commercial	PA is still required.

		<u>Liposuction or Lipectomy</u> **Policy clarified.** ▪ Medically necessary statements on Liposuction or Lipectomy updated to state: including, but not limited to lipedema under Disease (last bullet). ▪ Prior authorization table was updated to indicate that PA is required for liposuction/lipectomy for: Commercial PPO and EPO; and Commercial Managed Care (HMO and POS). The PA table was updated to include a separate column for Commercial Indemnity.	August 9, 2023		
Gender Affirming Services (Transgender and Gender Diverse Services)	189	**Policy revised.** Investigational/non-covered services added to non-covered section. Coding section clarified.	December 1, 2023	Commercial Medicare	Prior authorization **is still required**.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Gene Therapies for Duchenne Muscular Dystrophy	022	**New medical policy** describing medically necessary and investigational indications. 025 Prior Authorization Request Form for Duchenne Muscular Dystrophy.pdf	August 9, 2023	Commercial Medicare	PA is required.
Gene Therapies for Hemophilia B	168	**Policy revised.** Updated criteria for medical necessity to include:	August 9, 2023	Commercial Medicare	PA is still required.

		• physician attestation and historical records or chart notes to establish severity of hemophilia B; • greater than 150 prior exposure days to treatment for current factor therapy criteria. 169 Prior Authorization Request Form for Gene Therapies for Hemophilia B.pdf			
Zolgensma (onasemnogene abeparvovec-xioi) for Spinal Muscular Atrophy (SMA)	008	**Policy revised.** • Updated number of SMN2 copies requirement from no more than 3 to 4. • Updated to match BCBSA updates - removed the weight requirement of ≤13.5kg at time of infusion; added new criteria requirement for baseline liver function. . 085 Prior Authorization Request Form for Zolgensma (onasemnogene abeparvovec-xioi) for Spinal Muscular Atrophy MP 008 prn.pdf	August 9, 2023	Commercial Medicare	PA is still required.
Vascular Endothelial Growth Factor (VEGF) Inhibitors Step Therapy	092	**Policy revised.** Removing Biosimilars as an option to use in Step 1.	December 1, 2023	Commercial	PA is still required.

PULMONOLOGY | INFECTIOUS DISEASE | CLINICAL LABORATORY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Pathogen Panel Testing	045	Respiratory Virus Panel **policy criteria revised.**	December 1, 2023	Commercial	PA is not required.

		Enforcement Update List of covered diagnoses codes added. New diagnoses-to-CPT codes edit to be implemented on December 1, 2023.			

August 2023

ANESTHESIOLOGY GASTROENTEROLOGY PULMONOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Monitored Anesthesia Care (MAC)	154	**Policy clarified.** American Society of Anesthesiology (ASA) Physical Status Classification examples added. The list of risk factors or significant medical conditions guidelines clarified. **Enforcement update** Diagnoses codes list added. New diagnoses-to-CPT codes edit to be implemented on January 1, 2024.	January 1, 2024	Commercial Medicare	Prior authorization is still not required.

MULTISPECIALTY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Hyperbaric Oxygen Therapy	653	**Policy revised** to include coverage for the treatment of compromised skin grafts and flaps to medically necessary statement.	November 1, 2023	Commercial	PA is still not required.

NEUROLOGY ORTHOPEDICS REHABILITATION

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Minimally	719	Policy statements	August 1,	Commercial	No action

Invasive Ablation Procedures for Morton and Other Peripheral Neuromas		**clarified.** Minimally invasive ablation procedures, including intralesional alcohol injection, radiofrequency ablation, and cryoablation are considered investigational for the treatment of Morton and other peripheral neuromas.	2023		required.

ONCOLOGY UROLOGY LABORATORY SERVICES

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Laboratory Testing Investigational Services	165	**New medical policy** describing ongoing investigational indications. All tests listed in this policy are considered investigational as there is insufficient evidence to determine that the technology results in an improvement in the net health outcome.	August 1, 2023	Commercial	No action required.
Multicancer Early Detection Testing	124	**New medical policy** describing investigational indications. The use of multicancer early detection (MCED) tests (e.g., Galleri) is considered investigational for cancer screening.	November 1, 2023	Commercial Medicare	No action required.

PLASTIC SURGERY ONCOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Recon-structive Breast Surgery/ Management of Breast	428	**Policy clarified.** Medically necessary statement on explantation of a silicone gel-filled breast implant clarified as an	August 1, 2023	Commercial	Prior authorization is still required.

Implants		adjunct to surgical treatment of breast cancer.			

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Immuno-globulins	310	**Policy criteria revised.** Updated criteria for Myasthenia gravis.	November 1, 2023	Commercial Managed Care (HMO and POS) PPO & Indemnity MEDEX with Rx plan Managed Major Medical with Custom BCBSMA Formulary Comprehen-sive Managed Major Medical with Custom BCBSMA Formulary Managed Blue for Seniors with Custom BCBSMA Formulary	Prior authorization is still required.

Carelon Guidelines Announcements | Announced August 2023

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 (row)	**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

Genetic Testing

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Carrier Screening in the Prenatal Setting and Preimplantation Genetic Testing	**General Requirements** **Carrier screening – standard and expanded** **Standard screening** Standard screening for cystic fibrosis (CFTR testing) and spinal muscular atrophy (SMN1 testing) using standard mutation panels is considered **medically necessary** for all women who are pregnant or considering pregnancy and their reproductive partners. **Expanded screening** Expanded carrier screening (i.e., multigene testing) is considered **medically necessary** when **ALL** of the following criteria are met: • The genetic disorders being screened for have clearly defined gene(s) and pathogenic variants associated with them • The test has sufficiently high sensitivity and specificity to guide clinical decision making • Alternate biochemical or other clinical tests are not available, have provided an indeterminate result, or are less accurate than genetic testing • The natural history of the disease is associated with significant morbidity and/or mortality in affected individuals • 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 • At least **ONE** of the following is present: ○ One or both individuals are members of a population (e.g., Ashkenazi Jewish, Mediterranean, and Southeast Asian, among others) that is known to be at increased risk for certain conditions (e.g., conditions that have carrier frequency of at least 1% in that population) ○ The reproductive couple is known or suspected to be consanguineous ○ One or both individuals do not have access to a biological family history due to adoption, use of reproductive donor, or other reasons *Note: Expanded carrier screening should be directed toward genes that are associated with family history and ethnicity. Additionally, genes included in the panel should be shown to impact patient management and health outcomes*. **Targeted carrier screening based on family history** Targeted carrier screening is considered **medically necessary** when **ANY** of the following criteria are met: • The individual has a previously affected child with the genetic condition being tested for • Either partner has a first-, second-, or third-degree relative who is affected with the genetic condition being tested for • The reproductive partner of the individual being tested is a known	November 5, 2023

	carrier of the gene associated with the condition being screened **Explanation of change** Expand targeted screening to third-degree relatives. All other changes are for clarity. **Exclusions** The following tests and clinical scenarios are considered **not medically necessary**: • Prenatal testing for conditions known to have adult onset • Cell-free DNA testing for single gene disorders, microdeletions, or other indications not otherwise specified • Variants with high allele frequencies and low penetrance of a phenotype (e.g., methylene tetrahydrofolate reductase variants) • Whole exome or whole genome assays for the purpose of carrier screening • Conditions for which screening performance with nonmolecular screening techniques (e.g., hereditary hemochromatosis has low penetrance when molecular variants are identified) **Explanation of change** Exclude whole exome and whole genome assays for carrier screening.	
Cell-free DNA Testing (Liquid Biopsy) for the Management of Cancer	**Cell-free DNA (ctDNA, Liquid Biopsy) Testing** **Individuals with metastatic breast cancer who may benefit from PIK3CA or ESR1-targeted therapy** Liquid (ctDNA) based panel with PIK3CA or ESR1 somatic tumor testing is considered **medically necessary** to identify individuals who may benefit from the use of alpelisib or elacestrant, respectively (or other FDA-approved targeted agent) when **ALL** of the following criteria are met: • The individual is either an adult man OR postmenopausal woman • The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for an applicable FDA-approved targeted agent • The individual has not had prior testing for the targeted gene of interest in the metastatic setting • There is insufficient tumor tissue available for NGS-based somatic profiling or tissue biopsy is considered contraindicated due to the individual's clinical condition **Individuals with metastatic adenocarcinoma of the prostate who may benefit from a PARP inhibitor or PD-1 inhibitor** Liquid (ctDNA) based panel tests are considered **medically necessary** for individuals with metastatic adenocarcinoma when **ALL** of the following criteria are met: • The individual has biopsy-proven adenocarcinoma of the prostate • The individual has not had prior NGS testing in the metastatic setting • The individual is a candidate for **ONE** of the following therapies: ○ FDA-approved PARP inhibitor (olaparib, rucaparib, or other approved PARP inhibitor) ○ FDA-approved PD-1 inhibitor (pembrolizumab, or other approved checkpoint inhibitor) • There is insufficient tumor tissue available for NGS-based somatic profiling or tissue biopsy is considered contraindicated due to the individual's clinical condition	November 5, 2023

	Explanation of change Expand on ESR1 ctDNA testing, per the FDA. Adjust for clarity and specification.	
Hereditary Cancer Testing	**Condition-Specific Requirements** **Adenomatous polyp syndromes** Germline genetic testing of the APC gene and/or MUTYH gene variants for susceptibility to invasive cancer due to adenomatous polyp syndromes is considered **medically necessary** when **EITHER** of the following criteria are met: ▪ The individual has a personal history of more than 10 cumulative colorectal adenomas • The individual's family history and/or clinical findings are suggestive of an inherited polyposis syndrome **Explanation of change** Clarifications. **Condition-specific Requirements** **Hereditary breast, ovarian, and pancreatic cancer (HBOP)** **BRCA1 and BRCA 2** Germline genetic testing panels that include BRCA1 and BRCA2 are considered **medically necessary** to aid in current systematic therapy and surgical decision-making in the following scenarios: [not all scenarios are included here] ▪ **Women** with **ANY** of the following risk profiles: ○ Inherited cancer susceptibility as determined by a validated BRCA1 or BRCA2 mutation assessment tool, including any of the following tools: Ontario Family History Assessment Tool; Manchester Scoring System; Referral Screening Tool; Pedigree Assessment Tool; 7-Question Family History Screening Tool; International Breast Cancer Intervention Study Instrument [Tyrer-Cuzick]; or BRCAPRO [brief version] ○ One or more first-degree relatives with breast cancer diagnosed at age 50 years and younger ○ One or more first- or second-degree relative with epithelial ovarian, fallopian tube, or primary peritoneal cancer ○ One or more first-degree relatives with bilateral breast cancer ○ One or more male first- or second-degree relatives with breast cancer ○ One or more first- or second-degree relatives with both breast and epithelial ovarian cancer ○ One or more first-, second-, or third-degree relatives with a known BRCA1 or BRCA2 pathogenic variant ○ One or more first- or second-degree relatives on the same side of the family with breast cancer **AND** one or more first- or second-degree relatives on the same side of the family with epithelial ovarian cancer ○ Two or more first- or second-degree relatives on the same side of the family with epithelial ovarian cancer ○ Two or more first- or second-degree relatives on the same side of the family with breast cancer, one of whom was diagnosed at age 50 years and younger ○ Three or more first- or second-degree relatives on the same side of the family with breast cancer	November 5, 2023

	○ Three or more first- or second-degree relatives from the same side of the family with breast or high-grade prostate cancer ○ Ashkenazi Jewish descent **AND** one or more first-degree relatives with breast cancer ○ Ashkenazi Jewish descent **AND** two or more second-degree relatives on the same side of the family with breast or epithelial ovarian cancer • **Men** with **EITHER** of the following risk profiles: ○ Two or more first-degree relatives with pancreatic cancer ○ Any first-, second-, or third-degree relative who has a known BRCA1 or BRCA2 pathogenic variant, where the results will influence reproductive decision-making **Explanation of change** Add mutation assessment tools (bullet 1) in compliance with state mandate. Raise age cutoff (bullet 2) to align with updated NCCN guidelines (V 3.2023), which parallels the USPSTF recommendation for moderate-risk population. Separate and edit criteria (3rd and last bullet) for clarity.	
Somatic Testing of Solid Tumors	**<u>Metastatic or Advanced Cancer (Tumor Agnostic Testing)</u>** **Tumor-agnostic testing for patients with advanced solid tumors** Multi-gene panel testing is considered **medically necessary** when **ALL** of the following are true: • The individual has a metastatic or advanced solid tumor and adequate performance status for cancer treatment • A genomic biomarker-linked therapy has been approved by the FDA for their cancer clinical scenario, or there are established genomic biomarker-based treatment contraindications or exclusions • There are no existing indications for the planned therapy such that its use does not depend on the results of genetic testing (i.e., immune checkpoint inhibitor indications) • There are no satisfactory tumor-specific standard therapies available • Testing falls into **ANY** of the following categories: ○ Mismatch-repair (MMR) deficiency ▪ MLH1, MSH2, MSH6, PMS2 or EPCAM genes by PCR or NGS testing ▪ FDA-approved Microsatellite testing (MSI) and/or dMMR testing ▪ MLH-1 promoter methylation and/or BRAF V600E mutation testing with nuclear expression loss of MLH1 and PMS2 by immunohistochemistry ○ Tumor mutational burden (TMB) testing ○ NTRK and RET fusion testing ○ BRAF V600E mutation testing **Explanation of change** Adjust for clarification. Expand to cover RET, per FDA. **<u>Cancer-specific Criteria</u>** **Breast Cancer** Localized breast cancer Gene expression profiling is considered medically necessary for individuals with localized breast cancer using Oncotype DX, MammaPrint, EndoPredict, Prosigna Breast Cancer Prognostic Gene	November 5, 2023

	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) **Explanation of change** Adjust for clarification. **Cancer-specific Criteria** **Breast Cancer** Metastatic breast cancer Testing for somatic pathogenic variants of PIK3CA is considered **medically necessary** for postmenopausal women and adult males when **ALL** of the following criteria are met: • The individual has ER-positive and HER2-negative metastatic breast cancer • The individual is a candidate for alpelisib or another FDA-approved PIK3CA-targeted agent • The individual has not had prior testing for PIK3CA in the metastatic setting Testing for somatic pathogenic variants of ESR1 is considered **medically necessary** for postmenopausal women and adult males when **ALL** of the following criteria are met: • The individual has ER-positive and HER-negative metastatic breast cancer • The individual is a candidate for treatment for elacestrant per the FDA label • The individual has not had prior testing for ESR1 in the metastatic setting *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario. See the Tumor Agnostic Testing guideline for details.* **Explanation of change** *Adjust for clarification. Expand to cover ESR1, per FDA.* **Cancer-specific Criteria** **Endometrial carcinoma, advanced**	

	Tissue-based somatic tumor testing is considered **medically necessary** for individuals with advanced endometrial carcinoma and may be performed on the primary tumor or a metastatic site when **ALL** of the following criteria are met: • The individual has biopsy-proven endometrial carcinoma • Assessment includes the following, as applicable: ○ FDA-approved MSI-H and/or dMMR mismatch repair testing ○ MLH-1 promoter methylation testing with IHC nuclear expression loss of MLH1 and PMS2 • There has been no prior testing *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario. See the Tumor Agnostic Testing guideline for details. Additionally, for MLH1 germline testing for Lynch Syndrome, please refer to the Hereditary Cancer Testing guideline.* **Explanation of change** Adjusted for clarification by creating its own testing scenario. **Cancer-specific Criteria** **Non-Small Cell Lung Cancer** Metastatic NSCLC Tissue-based NGS panel testing is considered **medically necessary** to identify pathogenic variants in individuals with stage IIIB, IIIC, or metastatic NSCLC when **ALL** of the following criteria are met: • Biopsy-proven NSCLC with **EITHER** of the following characteristics: ○ An adenocarcinoma component on histology ○ Non-squamous, non-small cell histology • The panel testing contains, at minimum, testing of appropriate molecular aberrations (mutations, rearrangements, fusions, or amplifications) in ALL of the following genes: EGFR, ALK, ROS1, BRAF, ERBB2 (HER2), KRAS, MET, NTRK, and RET • The individual is a candidate for targeted therapy that may be prescribed based on the panel test results • The individual has not had prior NGS testing in the metastatic setting *Note: Tumor agnostic genetic testing indications may also apply, depending on the clinical scenario. See the Tumor Agnostic Testing guideline for details.* **Explanation of change** Adjust to address copy and paste error. **Cancer-specific Criteria** **Chronic Myeloid Leukemia (CML)** Bone marrow tissue-based or peripheral blood somatic genetic testing is considered **medically necessary** for establishing the diagnosis of suspected CML when the following criterion is met: • PCR or FISH testing includes the evaluation of the BCR-ABL1 fusion gene BCR-ABL kinase domain point mutation analysis is considered **medically necessary** in the monitoring of CML in **ANY** of the following circumstances: • Evaluation of individuals with chronic myelogenous leukemia to evaluate treated individuals who manifest suboptimal response to tyrosine kinase inhibitor therapy indicated by:	

	○ Lack of a partial hematologic or cytogenetic response at 3 months or greater after treatment onset ○ Less than a complete hematologic and cytogenetic response at 12 months ○ Disease progression to accelerated or blast phase **Explanation of change** Expand specimen type to include peripheral blood. Adjust for clarity and separate out MPNs into its own section. **Cancer-specific Criteria** **Myeloproliferative Neoplasms (MPN)** Bone marrow tissue-based or peripheral blood somatic genetic testing is considered **medically necessary** for establishing the diagnosis of suspected MPN (e.g., essential thrombocytosis, polycythemia vera, chronic neutrophilic leukemia, and primary myelofibrosis) when **BOTH** of the following criteria are met: • PCR, FISH, or NGS testing is targeting applicable JAK2, CALR, CSF3R, and MPL genes • **ONE** of the following clinical scenarios: ○ Hemoglobin ≥16.5 g/dL in male and hemoglobin ≥ 16.0 g/dL in female ○ Hematocrit greater than 49% in male and hematocrit greater than 48% in female ○ Platelet count ≥450 X 109/L ○ Leukocytosis (white blood cell) ≥11 X 109/L **Explanation of change** Adjust for clarity and separate out MPNs into its own section. Define peripheral blood indices, as alluded to in the rationale.	

July 2023

CARDIOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Leadless Cardiac Pacemakers	038	**Policy revised.** Medically necessary statements were added for Aveir and Micra AV transcatheter pacing systems with criteria. Medical necessity criteria were updated for both Micra and Aveir devices based on labeled indications for use and responses to structured requests for clinical input.	October 1, 2023	Commercial	No action required.

PEDIATRICS

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

Diagnostic Laboratory Services	139	**Policy revised** to include the following note under complete blood count: Children ages 0-4 are covered for anemia screening when billed with 85027.	October 1, 2023	Commercial	No action required.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Gene Therapies for Bladder Cancer	159	**New medical policy** describing medically necessary and investigational indications. Prior Authorization request Form for Adstiladrin (nadofaragene firadenovec-vncg), #193	June 8, 2023	Commercial Medicare	Prior authorization is required.
Entyvio (Vedolizumab)	162	**Policy criteria revised**.	June 1, 2023	Commercial	Prior authorization is still required.
Immune Modulating Drugs	004	**Policy criteria revised.**	June 1, 2023	Commercial	Prior authorization is still required.

June 2023

ANESTHESIOLOGY GASTROENTEROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Monitored Anesthesia Care (MAC)	154	**Implementation postponed.** We previously notified you that effective for dates of service on or after July 1, 2023, we would implement diagnosis-driven claim edits to reinforce our existing monitored anesthesia care (MAC) medical policy 154 guidelines. After careful review, we have decided to postpone our	January 1, 2024	Commercial Medicare	Prior authorization is still not required.

		enforcement of this medical policy to January 1, 2024.			
Medical Technology Assessment Investigational (Non-Covered) Services List	400	**Policy clarified** to remove Bispectral Index (BIS®) Monitoring for Anesthesia Awareness	June 1, 2023	Commercial Medicare	No action required.

BEHAVIORAL HEALTH

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Digital Health Technologies: Therapeutic Applications	090	**New medical policy** describing investigational indications.	September 1, 2023	Commercial Medicare	No action required.

HEMATOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Gene Therapies for Hemophilia B	168	**Policy clarified** to align with the National policy. Updated criteria for medical necessity – age, assigned sex at birth, disease severity, FIX therapy requirements, exclusion criteria, baseline test requirements. Prior Authorization Request Form for Hemgenix® (Etranacogene dezaparvovec), #169	May 2, 2023	Commercial Medicare	Prior authorization is still required.

NEUROSURGERY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Intraoperative Neuro-physiologic Monitoring	211	**Policy clarified** on Intraoperative Neurophysiologic Monitoring. New	June 1, 2023	Commercial	Prior authorization is still required.

Sensory-Evoked Potentials, Motor-Evoked Potentials, EEG Monitoring		indication for spinal instrumentation requiring screws or distraction added. No changes to policy statement as **the new indication would be covered within the existing medically necessary policy statement** on intraoperative neurophysiologic monitoring during spinal, intracranial, or vascular procedures.			

OTOLARYNGOLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Steroid-Eluting Sinus Stents	800	**Policy revised** to include coverage for Sinuva when policy criteria are met.	September 1, 2023	Commercial Medicare	Prior authorization is not required.

PHARMACY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medicare Advantage Part B Step Therapy	020	Policy updated to include new LCD for Intraarticular Knee Injections of Hyaluronan (L39529).	June 11, 2023	Medicare	Prior authorization is still required.
Drugs for Weight Loss	572	Policy criteria revised.	September 1, 2023	Commercial	Prior authorization is still required.

Carelon Guidelines Announcements

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 (row)	**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

RADIOLOGY EXTREMITY IMAGING

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Extremity Imaging	**Trauma** Acute traumatic injuries –not otherwise specified **Fracture** • Lower extremity: ▪ Femoral neck, proximal femur ▪ Tibia (anterior/lateral/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) **Explanation of change** Added small clarification regarding patients in whom advanced imaging of suspected calcaneal fractures is indicated	September 10, 2023
Extremity Imaging	**Perioperative Imaging, unspecified** **Shoulder arthroplasty, presurgical planning** **IMAGING STUDY** • MRI upper extremity (joint) for assessment of rotator cuff status or for planned reverse shoulder arthroplasty • CT upper extremity (joint) for preoperative assessment of bone stock and bone version, or for planned reverse shoulder arthroplasty **Explanation of change** Clarified that MRI should not be used for preoperative assessment of bone stock and bone version	September 10, 2023

RADIOLOGY SPINE IMAGING

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Spine Imaging	**Infectious and Inflammatory Conditions** **Spinal infection** *Includes epidural abscess, arachnoiditis, discitis, and vertebral osteomyelitis.* Advanced imaging of the spine is considered medically necessary in **EITHER** of the following scenarios: • Diagnosis in patients with new or worsening spinal pain or	September 10, 2023

	neurological abnormalities, and **ANY** of the following: ○ Documented fever ○ Elevated ESR or CRP ○ Known bloodstream infection ○ **ANY** of the following risk factors: ▪ Diabetes mellitus ▪ Intravenous drug use ▪ Malignancy ▪ HIV ▪ Dialysis ▪ Recent spinal intervention (examples include: surgery with or without hardware placement, stimulator implantation, or pain injection) ▪ Decubitus ulcer or wound overlying the spine **Explanation of change** Added criterion for imaging in patients at risk for infection, based on ACR appropriate use criteria (Ortiz, 2021)	
Spine Imaging	**Trauma** **Cervical injury** ***ADULT*** **IMAGING STUDY** • CT cervical spine for initial diagnosis or management • MRI cervical spine for management of trauma, except follow up of known fracture ***PEDIATRIC*** **IMAGING STUDY** • CT cervical spine for initial diagnosis, or for diagnosis or management of trauma • MRI cervical spine for diagnosis or management of trauma **Explanation of change** Added language to clarify modality appropriateness	September 10, 2023
Spine Imaging	**Thoracic or lumbar injury** **IMAGING STUDY** • CT thoracic or lumbar spine for initial diagnosis or for management • MRI thoracic or lumbar spine for management of trauma, except follow up of symptomatic fracture **Explanation of change** Added language to clarify modality appropriateness	September 10, 2023
Spine Imaging	**Signs and Symptoms** **Radiculopathy** **IMAGING STUDY** • CT cervical, thoracic, or lumbar spine when MRI cannot be performed or is nondiagnostic; or when being done as CT myelography • MRI cervical, thoracic, or lumbar spine **Explanation of change** Added indication for CT being done as a CT myelogram, based on ACR rating of "may be appropriate" (Hutchins, 2021) plus feedback from subject matter experts	September 10, 2023

RADIOLOGY VASCULAR IMAGING

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

CARELON GUIDELINE	POLICY CHANGE SUMMARY	EFFECTIVE DATE
Vascular Imaging	**Procedure-related Imaging** **Vascular anatomic delineation prior to surgical and interventional procedures, not otherwise specified*** **IMAGING STUDY** • CTA head, neck, chest, abdomen and pelvis, or extremities (based on specific procedure) MRA head, neck, chest, abdomen and pelvis, or extremities (based on specific procedure) ***Exclusions:** stenting or angioplasty of the dural venous sinus **Explanation of change** Removed to align with added allowances below for Duplex carotid and CTA/MRA neck	September 10, 2023
Vascular Imaging	**Vascular evaluation prior to transcatheter aortic valve implantation/replacement (TAVI/TAVR)** **IMAGING STUDY** • Duplex arterial ultrasound for carotid artery evaluation • CT or CTA chest, abdomen and pelvis; CTA neck requires initial duplex arterial ultrasound • MRA chest, abdomen and pelvis; MRA neck requires initial duplex arterial ultrasound **Explanation of change** Allow CT in addition to CTA for preop TAVR evaluation (contrast-enhanced CT sufficient for evaluation).	September 10, 2023
Vascular Imaging	**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 ○ Evaluation prior to cardiac surgery when needed to determine surgical strategy • 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 ○ Initial baseline evaluation, and one additional evaluation during the first year following carotid revascularization **Explanation of change** Screening: Limitation to preoperative evaluation prior to cardiac surgery	September 10, 2023

	Management: Clarification to allow follow-up per current ACC guidelines (addresses content gap for allowable 9–12-month eval)	
Vascular Imaging	**Chest** **Pulmonary hypertension** Advanced imaging is considered medically necessary for diagnosis and management in **EITHER** of the following scenarios: • To evaluate suspected pulmonary hypertension, including chronic thromboembolic pulmonary hypertension (CTEPH) • To evaluate disease extent after diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) in patients being considered for surgery **Explanation of change** Clarification of heading indication and allowance for evaluation of suspected PH (any etiology)	September 10, 2023
Vascular Imaging	**Abdomen and Pelvis** **Unexplained hypotension** Vascular imaging is considered medically necessary for evaluation of volume status in patients with unexplained hypotension. **IMAGING STUDY** • Duplex ultrasound of the IVC **Explanation of change** Removal of indication more appropriate for inpatient assessment	September 10, 2023
Vascular Imaging	**Venous thrombosis or occlusion** **IMAGING STUDY** • Duplex ultrasound • CTA abdomen or CTA abdomen/pelvis • MRA abdomen with or without MRA pelvis **Explanation of change** Addition of Duplex ultrasound as a modality option (no content change – allowance currently operationalized in system)	September 10, 2023
Vascular Imaging	**Lower Extremity** **Peripheral arterial disease (PAD)** Management of known PAD in **ANY** of the following scenarios: • Prior diagnosis of PAD with **ANY** of the following new or worsening signs or symptoms: ○ Resting ischemic pain, non-healing wounds, and gangrene ○ Ischemic or discolored toes, and livedo reticularis ○ Sudden onset of pain associated with pulselessness, pallor, loss of motor or sensory function • Persistent claudication following a trial of 3 months of conservative therapy including a supervised exercise therapy program in patients being evaluated for initial revascularization • Post revascularization with any new or worsening lower extremity non-joint pain not addressed above, following nondiagnostic physiologic testing (physiologic testing not required if venous graft was used) • Post revascularization when surveillance physiological testing is inconclusive (ABI > 1.40), borderline (ABI 0.91–0.99), or abnormal (ABI ≤ 0.90)	September 10, 2023

	• Baseline evaluation after surgical revascularization using a venous graft or after endovascular revascularization (angioplasty, stent, or atherectomy) **Surveillance** • After surgical revascularization using a venous graft: At 3-month intervals within the first 2 years, and annually thereafter • After endovascular revascularization (angioplasty, stent, or atherectomy): At 4-month intervals within the first year, and annually thereafter **Explanation of change** Removal of cilostazol as prerequisite therapy (specialty panel feedback). Addition of baseline evaluation & surveillance indications post endovascular revascularization. (Post-venous graft surveillance moved to "Surveillance" section; no content change).	
Vascular Imaging	**Popliteal artery aneurysm** Advanced imaging is considered medically necessary in **ANY** of the following scenarios: • Diagnosis of suspected aneurysm • Management for known aneurysm with signs or symptoms suggestive of change in size or patency • Surveillance for: ○ Unrepaired aneurysms less than 2 cm, in patients who are candidates for revascularization: annually ○ Following open or endovascular repair at 3, 6, and 12 months following repair, then annually **Explanation of change** Addition of diagnosis/management and unrepaired surveillance scenarios, the latter aligned with SVS guidelines	September 10, 2023

SLEEP DISORDER MANAGEMENT

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
Sleep Disorder Management	**Home Sleep Testing** Home sleep apnea test/study **Explanation of change** Change terminology throughout guidelines to home sleep “apnea” study to be more expansive and specific	September 10, 2023
Sleep Disorder Management	**Contraindications to Home Sleep Apnea Studies** Chronic opiates when discontinuation is not an option. Diagnostic sleep testing for patients using opiates for acute self-limited conditions should ideally be deferred until the medications have been stopped **Explanation of change** Change opiate terminology to current definition and usage	September 10, 2023
Sleep Disorder	**In-Lab (Attended) Sleep Studies in Adult Patients (Age 19 Years or Older)**	September 10, 2023

Management	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 • Narcolepsy • Nocturnal seizures • Parasomnia • 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, or continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep apnea testing • Nocturnal desaturation (due to severe COPD or certain restrictive thoracic disorders) • Any of the following conditions (right heart failure, polycythemia, cardiac arrythmias occurring solely during sleep, or pulmonary hypertension) when the etiology is unclear **Explanation of change** Modified language to be more restrictive of conditions	
Sleep Disorder Management	**Established sleep disorder (OSA or other) – follow-up laboratory studies** 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: • To assess efficacy of surgery (adenotonsillectomy or upper airway surgery) or oral appliances/devices in a patient with a contraindication to a home sleep apnea study • … • To optimize device settings on one occasion following insertion of a hypoglossal or phrenic nerve stimulator **Explanation of change** Modified language to be more expansive and specific	September 10, 2023
Sleep Disorder Management	**Contraindications to APAP** Moderate or severe chronic obstructive pulmonary disease: FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted **Explanation of change** Add more specific parameters to COPD	September 10, 2023
Sleep Disorder Management	**Bi-Level Positive Airway Pressure (BPAP) Devices** **BPAP (with or without back-up rate feature) for patients with obesity hypoventilation syndrome)** Obesity Hypoventilation Syndrome (OHS) 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. **Explanation of change** New indication is expansive and includes OHS definition	September 10, 2023

Sleep Disorder Management	**Ongoing treatment with BPAP** Ongoing treatment with BPAP for obstructive or central 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 • Clinical evidence that demonstrates continued clinical benefit from use of the PAP device is submitted by the treating provider * 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** Add more expansive and specific language for BPAP usage	September 10, 2023
Sleep Disorder Management	**Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing** **Initial MSLT and/or MWT are considered medically necessary for suspected narcolepsy when BOTH of the following criteria are met:** • Daytime hypersomnolence 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 PSG or HSAT and symptoms persist despite adequate treatment of obstructive sleep apnea (if present) **Explanation of change** Add clarifications to be more expansive and specific	September 10, 2023
Sleep Disorder Management	**MSLT and/or MWT are considered medically necessary for idiopathic hypersomnia when BOTH of the following criteria are met:** • Daytime hypersomnolence has been present for at least 8 weeks • The patient has at least ONE of the following: ○ Difficult morning awakening ○ Prolonged sleep during primary sleep period ○ Sleep drunkenness ○ Frequent non-refreshing daytime naps ○ The patient has undergone PSG or HSAT and symptoms persist despite adequate treatment of obstructive sleep apnea (if present) **Explanation of change** Add clarifications to be more expansive and specific	September 10, 2023