MASSACHUSETTS

MEDICAL POLICY ANNOUNCEMENTS

Posted November 2024

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

Carelon

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

BEHAVIORAL HEALTH

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Zulresso (Brexanolone) for the Treatment of Post-Partum Depression	147	**Policy clarified.** Coverage for Zurzuvae added. This oral drug is covered through the pharmacy benefits.	November 1, 2024	Commercial Medicare	Prior authorization is required.

GENERAL SURGERY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Treatment of Varicose Veins/Venous Insufficiency	238	**Policy clarified.** The first policy statement under symptomatic varicose tributaries section was edited for clarity.	November 1, 2024	Commercial Medicare	Prior authorization is required.

MULTISPECIALTY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Hyperbaric Oxygen Therapy	653	**Policy revised** to include medically necessary treatment of: • necrotizing soft tissue infections • Idiopathic sudden sensorineural hearing loss • Central retinal artery occlusion. Added to investigational indications: acute peripheral artery insufficiency (outside of other listed medically necessary indications involving arterial insufficiency).	February 1, 2025	Commercial	No action required. Prior authorization is not required.

NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Remote Electrical Neuromodu-lation for Migraines	140	**New medical policy** describing medically necessary indications for remote electrical neuromodulation using Nerivio™.	February 1, 2025	Commercial Medicare	No action required. Prior authorization is not required.

PEDIATRICS

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Treatment of Congenital Athymia	**108**	**New medical policy** describing medically necessary and investigational indications.	February 1, 2025	Commercial Medicare	No action required. Prior authorization is not required.

PHARMACY - NEUROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Monoclonal Antibodies for Treatment of Alzheimer's Disease	946	**Policy clarified** to include that per label, Donanemab is administered every four weeks as an intravenous infusion over approximately 30 minutes. Product label of donanemab recommends obtaining an MRI prior to the second, third, fourth, and seventh infusions.	October 3, 2024	Commercial	Prior authorization is required for Lecanemab and Donanemab.

Carelon Guidelines. Effective March 23, 2025

Advanced Imaging/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

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

Carelon Guideline	Policy Change Summary	Effective Date
General Abdominal and Pelvic Indications		
Tumor or Neoplasm – not otherwise specified	**Tumor or Neoplasm – not otherwise specified** **IMAGING STUDY** ***ADULT*** • Ultrasound required for initial evaluation of a palpable pelvic mass in patients assigned female at birth, or for testicular masses in patients assigned male at birth • CT abdomen and/or pelvis for all other scenarios, or following nondiagnostic pelvic ultrasound • MRI abdomen for further characterization of abdominal mass seen on prior imaging, including CT scan **Explanation of change** Added requirement for initial evaluation of testicular masses with ultrasound prior to advanced imaging	March 23, 2025
Female Reproductive System and Obstetric Indications		
Endometriosis	**Endometriosis** Advanced imaging is considered **medically necessary** in EITHER of the following scenarios: • Diagnosis of clinically suspected endometriosis following nondiagnostic pelvic ultrasound • Management of established endometriosis **Explanation of change** Removed requirement for initial ultrasound in patients with established endometriosis	March 23, 2025
Obstetric Indications	**Obstetric Indications** **IMAGING STUDY** • Ultrasound is required for initial evaluation of fetal and placental conditions • Fetal MRI in the second or third trimester of pregnancy, for indications involving the fetus or placenta, following nondiagnostic ultrasound	March 23, 2025

	• MRI pelvis for pelvimetry or other obstetrical complications **Explanation of change** Specified that fetal MRI should be done in the second or third trimester	
	Hepatobiliary Indications	

Diffuse liver disease	**Diffuse liver disease**
	IMAGING STUDY
	• CT abdomen for **EITHER** of the following:
	  ○ Suspected liver disease
	  ○ Iron overload in hemochromatosis when MRI cannot be performed or is nondiagnostic
	• MRI abdomen for evaluation of hemochromatosis
	• MR elastography for diagnosis and management of advanced hepatic fibrosis/cirrhosis
	
	Explanation of change
	Removed the criteria for LiverMultiScan as an alternative to MR elastography due to lack of data indicating a change in management.
		March 23, 2025

	Pancreatic Indications	
Pancreatic mass, indeterminate cystic (including suspected IPMN/IPMT)	**Pancreatic mass, indeterminate cystic (including suspected IPMN/IPMT)** **Explanation of change** Clarified that this indication is meant to apply only to indeterminate cystic lesions, including when IPMN is suspected. Known IPMN should be reviewed using the Tumor or Neoplasm NOS indication.	March 23, 2025
	Nonspecific Signs and Symptoms	

Abdominal and/or pelvic pain, undifferentiated	**Abdominal and/or pelvic pain, undifferentiated**
	ADULT
	Advanced imaging is considered medically necessary in **EITHER** of the following scenarios:
	• Acute abdominal pain associated with clinical findings of a surgical abdomen, including severe undifferentiated abdominal pain or guarding or that remains unexplained after ALL of the following:
	  ○ History
	  ○ Physical exam
	  ○ Relevant lab results*
	  ○ Ultrasound if the pain localizes to the right upper quadrant (abdominal ultrasound) or female pelvis (pelvic ultrasound)
	• Nonacute abdominal pain that remains unexplained after ALL of the following:
	  ○ History
	  ○ Physical exam
	  ○ Relevant lab results*
	  ○ Ultrasound if the pain is localized to the right upper quadrant (abdominal ultrasound) or female pelvis (pelvic ultrasound)
		March 23, 2025

	○ Upper endoscopy if the pain is epigastric unless associated with elevated inflammatory markers (leukocytosis, C-reactive protein [CRP]) ○ Colonoscopy if the pain is associated with defecation and a change in the form and frequency of stools (i.e., irritable bowel syndrome) ***PEDIATRIC*** Advanced imaging is considered medically necessary for diagnosis in **ANY** of the following scenarios: • Acute abdominal pain associated with clinical findings of a surgical abdomen, including severe undifferentiated abdominal pain or guarding or that remains unexplained after ALL of the following: ○ History ○ Physical exam ○ Relevant lab results* ○ Abdominal or pelvic ultrasound • Chronic or recurrent pelvic pain following nondiagnostic ultrasound • Chronic or recurrent abdominal pain following nondiagnostic ultrasound when **ANY** of the following red flag signs are present: ○ Chronic severe diarrhea (at least 3 watery stools per day for more than 2 weeks) ○ Deceleration of linear growth ○ Fever of unknown origin ○ Gastrointestinal bleeding ○ History of a genetic or congenital syndrome ○ Immunocompromised ○ Involuntary weight loss ○ Persistent focal abdominal pain, especially right upper or right lower quadrant ○ Persistent vomiting ○ Elevated inflammatory markers (leukocytosis, C-reactive protein [CRP]) *Preliminary lab tests may include metabolic profile, complete blood count (CBC), C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and/or urinalysis. **Explanation of change** Removed general prerequisite for "prior imaging where available," as the intent is already addressed by the more specific requirements for US depending on pain location. Clarified language around lab (intent is that some preliminary lab testing is always appropriate).	

	Imaging of the Chest Guidelines	
	Tumor or Neoplasm	
Lymphadenopathy	**Lymphadenopathy** See *Oncologic Imaging for patients with documented malignancy. Thoracic lymphadenopathy is defined as at least one lymph node greater than 1 cm in short axis diameter.*	March 23, 2025

	Advanced imaging is considered **medically necessary** for diagnosis, management, or surveillance in **ANY** of the following scenarios:
	• Palpable thoracic or supraclavicular lymph nodes, when not amenable to percutaneous biopsy
	• Associated clinical or lab findings suggestive of malignancy, especially lymphoma or testicular carcinoma
	• Mediastinal or hilar lymph nodes when **ANY** of the following is present:
	  ○ Suspected by non-advanced imaging (i.e. chest radiography)
	  ○ Single follow up at least 3 months after discovery of nodes with a short axis diameter greater than 1.4 cm without suspicious features
	  ○ Lymphadenopathy with suspicious features:
	  ▪ Necrosis
	  ▪ Loss of fatty hilar morphology
	  ▪ Heterogenous or hypervascular enhancement
	  ▪ Irregular borders
	  ▪ Interval enlargement
	  ▪ Multiple enlarged nodes on the same side of the mediastinum (ipsilateral/unilateral)
	
	Explanation of change
	Moved the criterion for clinical/lab findings suggestive of malignancy as this does not apply only to mediastinal/hilar lymphadenopathy. No change in intent.	

	Signs and Symptoms	
Dyspnea	**Dyspnea** Advanced imaging is considered medically necessary when **BOTH** of the following apply: • Dyspnea is not explained by cardiac evaluation • Dyspnea is not explained by chest radiography **IMAGING STUDY** • CT chest **Rationale** The differential diagnosis for dyspnea is broad, but most etiologies are cardiovascular or pulmonary. When cardiac evaluation, generally including clinical examination and transthoracic echocardiography, has not revealed a cause for the dyspnea, pulmonary causes including asthma, bronchitis, chronic obstructive pulmonary disease, and interstitial lung disease are often considered in the differential diagnosis. Chest radiography is often able to guide further evaluation and can in some cases provide a specific diagnosis. When chest radiography is normal despite persistent clinical symptoms, or when chest radiography reveals an abnormality which requires further characterization, CT is a useful study. The American College of Radiology Appropriateness Criteria note that the protocol can be tailored to include adjuncts such as expiratory images or prone images, so knowledge of the clinically suspected diagnosis is helpful for planning of CT imaging. **Explanation of change**	March 23, 2025

	Added an indication for dyspnea to account for requests submitted without a differential diagnosis.	

	Oncologic Imaging Guidelines	
	Cancer Screening	
Colorectal cancer screening (CT colonography)	**Colorectal cancer screening (CT colonography)** **Average risk:* - No personal history of colonic adenoma, serrated sessile polyp/lesion (SSP/SSL), or colorectal cancer (CRC) - No personal history of inflammatory bowel disease, high-risk CRC genetic syndromes, cystic fibrosis, or childhood cancer - Negative family history for CRC, confirmed advanced adenoma (i.e. highgrade dysplasia, ≥ 1 cm, villous or tubulovillous histology or an advanced SSP/SSL) **Explanation of change** NCCN alignment for definition of average risk	March 23, 2025
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: • Family history of pancreatic cancer in ≥1 first-degree and ≥1 second-degree relatives*, starting at age 50 or 10 years earlier than the youngest affected relative *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** NCCN alignment for eligibility by family history	March 23, 2025
Hepatocellular carcinoma (HCC) screening	**Hepatocellular carcinoma (HCC) screening** CT or MRI Abdomen is indicated every 6 months as an alternative to abdominal ultrasound in patients with Hepatitis B or cirrhosis (any etiology) when ultrasound cannot be performed or is nondiagnostic. **Explanation of change** NCCN alignment (interval of screening imaging)	March 23, 2025

	Anal Cancer	
CT chest, CT abdomen and pelvis	**CT chest, CT abdomen and pelvis** Surveillance: Indicated no more than annually (stage II-III) **MRI pelvis** Surveillance: Indicated no more than annually (stage II-III) **Explanation of change** CT: NCCN alignment (surveillance intervals)	March 23, 2025

	Bladder and Urothelial Cancers	
Bladder/Urothelial Cancers: Non-muscle Invasive	**Bladder/Urothelial Cancers: Non-muscle Invasive** **CT chest** Surveillance: Not indicated **CT abdomen and pelvis** Surveillance: Indicated no more than every 12 months	March 23, 2025

	Bladder/Urothelial Cancers: Muscle Invasive **CT chest, CT abdomen and pelvis** Surveillance: Indicated no more than every 6 months **FDG- /CT** Diagnostic Workup: Indicated when standard imaging cannot be performed or is nondiagnostic for metastatic disease **Explanation of change** CT - NCCN alignment (surveillance intervals, Chest imaging for NMIBC); FDG PET: NCCN 2B recommendation, aligned with standard imaging approach	

	Breast Cancer	
CT chest, CT abdomen and pelvis	**CT chest, CT abdomen and pelvis** Diagnostic Workup: Indicated for at-risk* or clinically suspected metastatic disease **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 ○ Heterogeneously or extremely dense breasts ○ Breast cancer diagnosis before age 50 **FDG-PET/CT** Diagnostic Workup: Indicated when standard imaging cannot be performed or is nondiagnostic for metastatic disease **Tumor size >2 cm (T2), positive lymph nodes, tumor size >1 cm (T1c) and HER2+, or triple-negative disease* **Explanation of change** NCCN alignment (addition of risk subtypes for initial CT staging, MRI Breast surveillance, FDG PET staging)	March 23, 2025

	Cervical Cancer	
FDG-PET/CT	**FDG-PET/CT** Diagnostic Workup: Indicated for patients with stage IB1 or higher disease, or small cell neuroendocrine carcinoma of the cervix, as an alternative to CT chest, abdomen, and pelvis Management: Indicated in **ANY** of the following scenarios: • Single treatment response evaluation following radiation or chemoradiation when performed at least 12 weeks following completion of therapy Surveillance: Indicated for small cell neuroendocrine carcinoma of the cervix only **Explanation of change** FDG PET: NCCN alignment (small cell NECC diagnostic workup/surveillance); clarification of management (no operational change)	March 23, 2025

	Colorectal Cancer	
MRI pelvis	**MRI pelvis**	March 23, 2025

	Surveillance: Indicated no more than every 6 months for rectal cancer treated with transanal local excision or nonoperative management **FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • CT/MRI is equivocal for metastatic disease and lesion(s) is/are greater than 1 cm in diameter **Explanation of change** MRI - NCCN alignments (surveillance interval, addition for nonoperative management) FDG-PET: Addition to account for lesions seen by MRI (eg post-liver directed therapy)	

	Esophageal and Gastroesophageal Junction Cancers	
CT chest, CT abdomen	**CT chest, CT abdomen** Surveillance: Indicated no more than every 6 months (T1b or greater) **FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Radiation planning for preoperative or definitive treatment only • Single assessment of response to primary (neoadjuvant) treatment when performed at least 5 weeks after completion of therapy **Explanation of change** CT - NCCN alignment (surveillance interval) FDG PET - NCCN alignment (to account for other perioperative treatment).	March 23, 2025

	Gastric Cancer	
CT chest, CT abdomen and pelvis	**CT chest, CT abdomen and pelvis** Surveillance: Indicated no more than every 6 months **FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Single assessment of response to primary (neoadjuvant) treatment, when performed at least 5 weeks after completion of therapy **Explanation of change** CT - NCCN alignment (surveillance interval) FDG PET - NCCN alignment (imaging interval, removal of imaging requirement)	March 23, 2025

	Head and Neck Cancer	
FDG-PET/CT	**FDG-PET/CT** Management: Indicated in **ANY** of the following scenarios: • Single treatment response evaluation, no sooner than 12 weeks after completion of radiation therapy or chemoradiation • Follow up of equivocal post-treatment PET scan, no sooner than 12 weeks after the last study **Explanation of change** FDG PET: NCCN alignment (treatment response, f/u of equivocal post-treatment PET)	March 23, 2025

	Hepatocellular and Biliary Tract Cancers	
CT chest, CT abdomen and pelvis	**CT chest, CT abdomen and pelvis** Surveillance: Indicated no more than every 6 months **MRI abdomen with or without MRCP** Surveillance: Indicated no more than every 6 months **Explanation of change** CT/MRI - NCCN alignment (surveillance intervals)	March 23, 2025

	Histiocytic Neoplasms	
FDG-PET/CT	**FDG-PET/CT** Diagnostic Workup: Indicated in patients with LCH, ECD, or RDD **Explanation of change** FDG PET: NCCN alignment (PET threshold)	March 23, 2025

	Kidney Cancer	
CT chest	**CT chest** Surveillance: Indicated for **ANY** of the following: • Ablation: no more than annually • Partial or total nephrectomy: no more than every 6 months • Stage III or IV disease	March 23, 2025
CT abdomen +/- pelvis, MRI abdomen	**CT abdomen +/- pelvis, MRI abdomen** Management: Indicated for **EITHER** of the following: • Baseline imaging after ablation, partial or total nephrectomy • Active surveillance of stage I renal cancer: within 6 months of initiation, then annually Surveillance: Indicated for ANY of the following: • After ablation, partial or total nephrectomy: no more than every 6 months • Stage III or IV disease **Explanation of change** CT/MRI - NCCN alignment (surveillance intervals)	March 23, 2025

	Lung Cancer – Small Cell	
FDG-PET/CT	**FDG-PET/CT** Management: Indicated for **EITHER** of the following scenarios: • Prior to initiation of radiation therapy • Standard imaging cannot be performed, or is nondiagnostic for recurrent or progressive disease **Explanation of change** FDG-PET: Addition of standard imaging allowance when further characterization needed	March 23, 2025

	Lymphoma – Non-Hodgkin and Leukemia	
	Chronic lymphocytic leukemia or small lymphocytic lymphoma **CT chest, CT abdomen and pelvis** Surveillance: Not indicated **Lymphoma – Non-Hodgkin: Indolent non-Hodgkin lymphoma**	March 23, 2025

	CT neck, CT chest, CT abdomen and pelvis Surveillance: Indicated in **EITHER** of the following scenarios: • Follicular, marginal zone/MALT, or mantle cell lymphoma: Every 6 months, up to 2 years following completion of treatment and every 12 months thereafter • All other subtypes: Every 6 months, up to 2 years following completion of treatment **Lymphoma – Non-Hodgkin: Intermediate and high grade non-Hodgkin lymphoma** **CT neck, CT chest, CT abdomen and pelvis** Surveillance: Indicated in **EITHER** of the following scenarios: • Follicular, marginal zone/MALT, or mantle cell lymphoma: Every 6 months, up to 2 years following completion of treatment, and every 12 months thereafter • All other subtypes: Every 6 months, up to 2 years following completion of treatment **Explanation of change** CT - NCCN alignments (surveillance imaging)	

	Multiple Myeloma	
FDG-PET/CT	**FDG-PET/CT** Diagnostic Workup: Indicated for multiple myeloma or solitary plasmacytoma* **Explanation of change** FDG-PET: NCCN alignment (indicated for patients suspected of having multiple myeloma or solitary plasmacytoma).	March 23, 2025

	Penile, Vaginal, and Vulvar Cancers	
FDG-PET/CT	**FDG-PET/CT** Diagnostic Workup: Indicated in **ANY** of the following scenarios: • Standard imaging cannot be performed or is nondiagnostic for metastatic disease • Staging of penile cancer when pelvic lymph nodes are enlarged on CT or MRI and needle biopsy is not technically feasible • Staging of vaginal cancer Management: Indicated in **ANY** of the following scenarios: • Radiation planning for preoperative or definitive treatment only • Single treatment response assessment following radiation when performed at least 12 weeks after completion of therapy • Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease • Restaging of local recurrence when pelvic exenteration surgery is planned **Explanation of change** FDG-PET: NCCN alignment (added initial staging vaginal cancer, RT response scenarios)	March 23, 2025

	Thyroid Cancer	
FDG-PET/CT	**FDG-PET/CT** Diagnostic Workup: Indicated for **ANY** of the following subtypes:	March 23, 2025

	• Anaplastic • Oncocytic carcinoma Management: Indicated in **ANY** of the following scenarios: • Follow up of anaplastic carcinoma • Suspected recurrent papillary, follicular, or oncocytic carcinoma when I-131 scan is negative (or has been negative in the past) and stimulated thyroglobulin level is > 2 ng/dL • Suspected recurrent medullary carcinoma when detectable basal calcitonin or elevated CEA, and standard imaging is negative **Somatostatin receptor (SSR) PET/CT** Diagnostic Workup: Indicated for medullary carcinoma when standard imaging cannot be performed or is nondiagnostic **Explanation of change** FDG and SSR PET - NCCN scenario alignments (initial staging/management)	

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 Testing **General requirements – Germline pathogenic variants not otherwise specified***		
*To be used only when a specific indication is not available.	****To be used only when a specific indication is not available.*** Genetic testing is considered **medically necessary when ALL** the following criteria are met: • The individual to be tested is either at significant risk for a genetic disorder (for example, based on family history) or suspected to have a known genetic condition or is known to have been inadequately tested for a suspected genetic condition ○ This may include but is not limited to a personal history of a tumor (somatic) pathogenic variant in one or more of these genes: BRCA1, BRCA2, BRIP1, MLH1, MSH2, MSH6, MUTYH, PALB2, PMS2, RAD51C, RAD51D, RET, SDHAF2, SDHB, SDHC, SDHD, TMEM127, TSC2, or VHL	March 23, 2025

	○ For individuals younger than age 30, this may include personal history of a pathogenic variant in one or more of these genes: APC, PTEN, RB1, or TP53 • Scientific literature has established that one or more genes have pathogenic variability associated with the genetic condition • The genetic test has established clinical utility such that a positive or negative result of the genetic test will significantly impact clinical management and will likely result in a net improvement in health outcomes **Explanation of change** Removed criteria stating that alternate biochemical tests are not available, have provided an indeterminate result, or are less accurate than genetic testing Listed specific examples of somatic test findings that, per ASCO guideline, should generate consideration of germline testing (clarification) Included examples of pathogenic variants for individuals age <30 (clarification) Confirmatory	
	Confirmatory genetic testing of the identified variant(s) is considered **medically necessary if ALL** of the criteria above are met and **EITHER** of the following apply: • An individual identified to have a pathogenic or likely pathogenic germline variant in genes with established clinical utility based on FDA approved direct-to-consumer genetic testing • An individual identified to have a pathogenic or likely pathogenic germline variant in genes with established clinical utility based on results of IRB approved clinical research studies Germline genetic testing for known familial pathogenic or likely pathogenic variants is considered medically necessary in the following scenarios: • Any first-, second-, or third-degree relative who has a known pathogenic or likely pathogenic variant, where the results have established clinical utility **Explanation of change** Expanded criteria to include confirmatory genetic testing for individuals identified to have a pathogenic or likely pathogenic germline variant in genes with established clinical utility based on results from direct-to-consumer genetic testing and/or results from an IRB approved clinical research study	March 23, 2025

	Adenomatous polyp syndromes	
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 ANY** of the following criteria are met: • The individual has a personal history of more than 10 cumulative colorectal adenomas	March 23, 2025

	• The individual has multifocal or bilateral congenital hypertrophy of retinal pigment epithelium (CHRPE) • The individual has a first- or second-degree relative with a known pathogenic variant in the APC or MUTYH gene • The individual has a first-, second- or third-degree relative with clinical findings suggestive of an inherited polyposis syndrome **Explanation of change** Added criteria for individuals with multifocal or bilateral congenital hypertrophy of retinal pigment epithelium (CHRPE) Added criteria for first-, second-, or third-degree relatives with known pathogenic variant or clinical findings suggestive of an inherited polyposis syndrome	

	Hamartomatous polyposis syndromes **Juvenile polyposis syndrome**	
Hamartoma-tous polyposis syndromes Juvenile polyposis syndrome	Genetic testing for SMAD4 and BMPR1A gene variants to evaluate for juvenile polyposis syndrome is considered **medically necessary when ANY** of the following criteria are met: • Five (5) or more juvenile polyps in the colon • Multiple juvenile polyps in other parts of the gastrointestinal tract • Any number of juvenile polyps in a person with a known family history of juvenile polyps • Individual is a first- or second-degree relative of a patient suspected of having or diagnosed with juvenile polyposis syndrome **Explanation of change** Increased testing requirement for number of juvenile polyps in the colon from three to five (restrictive)	March 23, 2025

	Cowden syndrome	

Cowden syndrome	Genetic testing for PTEN pathogenic variants to evaluate for Cowden syndrome is considered medically necessary when BOTH of the following criteria are met:
	• **EITHER** of the following pathognomonic criteria are present:
	  ○ Adult Lhermitte-Dulcos disease (cerebellar tumors)
	  ○ Multiple mucocutaneous lesions including **ANY** of the following:
	  ▪ Three or more trichilemmomas, at least one of which is biopsy-proven
	  ▪ Three of more acral keratoses (palmoplantar keratotic pits and/or acral hyperkeratotic papules)
	  ▪ Three or more mucocutaneous neuromas
	  ▪ Three or more oral papillomas (particularly on tongue and gingivae) which are biopsy- proven or diagnosed by a dermatologist
	• **THREE** (3) or more of the following conditions are present:
	  ○ Breast cancer
	  ○ Fibrocystic disease of the breast
	  ○ Non-medullary thyroid cancer
	  ○ Thyroid adenoma or multinodular goiter
	  ○ Endometrial cancer
		March 23, 2025

	○ Genitourinary tumors ○ Genitourinary malformations or testicular lipomatosis ○ Uterine fibroids ○ Any GI hamartomas or ganglioneuromas ○ Autism spectrum disorder ○ Intellectual disability with IQ ≤ 75 ○ Biopsy-proven trichilemmoma ○ Multiple palmoplantar keratoses ○ Multifocal cutaneous facial papules • **THREE** (3) or more of the following conditions are present: ○ Breast cancer ○ Fibrocystic disease of the breast ○ Non-medullary thyroid cancer ○ Thyroid adenoma or multinodular goiter ○ Endometrial cancer ○ Renal cell carcinoma ○ Colorectal cancer ○ Genitourinary malformations or testicular lipomatosis ○ Lipomas ○ Uterine fibroids ○ Any GI hamartomas or ganglioneuromas ○ Autism spectrum disorder ○ Intellectual disability with IQ ≤ 75 ○ Biopsy-proven trichilemmoma ○ Multiple palmoplantar keratoses ○ Multifocal cutaneous facial papules ○ Macular pigmentation of the glans penis ○ Vascular anomalies (including multiple intracranial developmental venous anomalies) ○ Macrocephaly (≥ 97th percentile: 58 cm for adult women, 60 cm for adult men) **Explanation of change** Clarified genitourinary tumors as renal cell carcinoma Added minor criteria to include colorectal cancer and lipomas to the list of conditions that may be present Removed duplicate “Macular pigmentation of the glans penis”	

	Lynch syndrome	
Lynch syndrome	Germline genetic testing of MLH1, MSH2, MSH6, PMS2 or EPCAM genes to evaluate for Lynch syndrome (a mismatch repair deficiency syndrome) is considered **medically necessary in ANY** of the following scenarios: • Known Lynch syndrome pathologic variant in a first- or second-degree relative • Personal history of a tumor with MMR deficiency based on somatic testing using PCR, NGS, or IHC • Immunohistochemistry (IHC) testing of colorectal cancer, endometrial cancer, or any other Lynch syndrome-associated cancer showing loss of expression of MSH2 or MSH6 (or both), or loss of expression of PMS2; or loss of expression of MLH1 and PMS2 without evidence of BRAF V600E pathogenic variant or MLH1 promoter methylation • Evidence of microsatellite instability (MSI-high) based on testing of colorectal cancer, endometrial cancer, or any other	March 23, 2025

	Lynch syndrome-associated cancer, and IHC testing showing loss of expression of MLH1 and PMS2 without evidence of BRAF V600E pathogenic variant or MLH1 promoter methylation
	• 5% or higher lifetime risk of Lynch syndrome based on a validated predictive model
	• Personal history of colorectal or endometrial cancer or any other Lynch syndrome-related cancer in **ANY** of the following scenarios:
	  ○ Individual is age 49 years or younger at diagnosis
	  ○ Presence of synchronous or metachronous colorectal cancer
	  ○ Known additional Lynch syndrome-related cancer (colorectal, endometrial, gastric, ovarian, pancreatic, urothelial, CNS glioma, biliary tract, small intestine, sebaceous adenomas or carcinomas, keratoacanthomas, or breast carcinomas with medullary features)
	• Family history which includes **ANY** of the following:
	  ○ At least one first-degree relative with colorectal or endometrial cancer diagnosed before age 50
	  ○ At least one first-degree relative with colorectal or endometrial cancer and another Lynch syndrome-related cancer
	  ○ Two or more first- or second-degree relatives on the same side of the family with Lynch syndrome-related cancers, with at least one diagnosed before age 50
	  ○ Three or more first- or second-degree relatives on the same side of the family with Lynch syndrome-related cancers
	
	Explanation of change
	MMR deficiency (dMMR) clarified to be demonstrable by PCR, NGS, or IHC
	Personal history criteria expanded to include any other Lynch syndrome related cancer, and specified which cancers are associated with Lynch syndrome
	Breast cancer with medullary features included as a Lynch-syndrome associated cancer
	Family history criteria based on multiple family members with Lynch syndrome related cancers specified only those on the same side of the family
	Parenthetical reference to selected predictive models about germline risk removed for consistency with other parts of the guideline	

	Li-Fraumeni syndrome	
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 (referencing the Chompret criteria, last updated in 2015): • Personal history of breast cancer diagnosed at or before age 30	March 23, 2025

	• Personal history of breast cancer diagnosed at or before age 45 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 or before age 45 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 or before age 45
	• Personal history of adrenocortical carcinoma, choroid plexus carcinoma, embryonal anaplastic rhabdomyosarcoma, or pediatric hypodiploid acute lymphoblastic leukemia
	• Individual has at least one first-, second-, or third-degree relative with a known TP53 pathogenic or likely pathogenic germline variant **AND** the affected family member meets at least ONE of the above personal history criteria for Li-Fraumeni syndrome
	• Individual has had a pathogenic or likely pathogenic variant of TP53 identified on tumor somatic testing **AND ONE** of the following applies:
	  ○ The individual meets one or more of the personal history criteria above
	  ○ The individual was diagnosed at or before age 29 with any cancer
	
	Explanation of change
	Added pediatric hypodiploid acute lymphoblastic leukemia to the personal history positive criteria
	Restricted testing criteria for testing as follow-up to TP53 positive somatic tumor test results Restricted testing criteria for testing of unaffected first-, second-, or third-degree relatives	

	Hereditary Breast, Ovarian, and Pancreatic Cancer (HBOP) **Hereditary breast, ovarian, and pancreatic cancers**	
	Explanation of change HBOP criteria explicitly divided into categories by disease. Distinguished personal history from family history, and when close blood relatives are included in family history criteria, specified inclusion of first-, second-, and third-degree relatives on same side of the family. Clarified the threshold for elevated risk to be ≥5% based on use of validated predictive models	March 23, 2025

	Hereditary breast cancer	
Individuals age ≤65 newly	**Individuals age ≤65 newly diagnosed with invasive breast carcinoma**	March 23, 2025

diagnosed with invasive breast carcinoma	Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary** for individuals age ≤65 within 12 months of a new diagnosis of invasive breast cancer to aid in therapy and surgical decision-making and/or for personal and family risk assessment.
	See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing.
	
	Individuals age >65 newly diagnosed with invasive breast carcinoma
	Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary** for individuals age >65 within 12 months of a new diagnosis of invasive breast cancer to aid in therapy and surgical decision-making and/or for personal and family risk assessment with **ANY** of the following criteria:
	• Individuals assigned male sex at birth
	• 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
	• Currently a candidate for PARP inhibitor therapy
	
	See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing.
	
	Individuals age ≤65 previously diagnosed with invasive breast carcinoma
	Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary** for individuals age ≤65 with invasive breast cancer diagnosed ≥12 months prior when **BOTH** of the following criteria are met:
	• There is recurrence or development of a new primary breast cancer (ipsilateral or contralateral)
	• The individual is considered a candidate for treatment with a PARP inhibitor
	See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing.
	
	Individuals with no current or prior diagnosis of breast carcinoma
	Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary** for individuals without a current or prior diagnosis of invasive breast cancer with **ANY** of the following criteria:
	• Personal or family history suggests the possibility of a pathogenic variant with **ANY** of the following:
	  ○ Personal history of epithelial ovarian cancer or pancreatic adenocarcinoma
	  ○ Risk of a pathologic or likely pathologic variant in BRCA1 or BRCA2 is ≥5% based on a validated predictive model	

	○ At least one first-, second-, or third-degree blood relative with breast cancer diagnosed at or before age 50 ○ At least one first-, second-, or third-degree blood relative with epithelial ovarian, fallopian tube, or primary peritoneal cancer ○ At least one first- or second-degree blood relative with multiple primary breast cancers (metachronous or synchronous) ○ At least one first-, second-, or third-degree blood relative on the same side of the family with breast cancer in an individual assigned male sex at birth ○ At least one first-, second-, or third-degree blood relative on the same side of the family with metastatic prostate cancer or high or very high-risk grade group of localized or locally advanced prostate cancer ○ Three or more first-, second-, or third-degree blood relatives on the same side of the family with invasive breast and/or prostate cancer ○ Individuals with at least two first-degree blood relatives with pancreatic cancer ○ Ashkenazi Jewish descent **AND** at least one first-degree blood relative with breast cancer ○ Ashkenazi Jewish descent **AND** two or more second-degree blood relatives on the same side of the family with breast or epithelial ovarian cancer ○ Individuals requiring confirmatory testing based on findings of BRCA1 or BRCA2 pathogenic or likely pathogenic germline variants found in other testing contexts including ANY of the following: ▪ 23andMe PGS (or similar FDA approved commercial direct-to-consumer testing) ▪ somatic testing for malignancy ▪ **IRB approved clinical research** See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing. **Explanation of change** • All women <65 with personal history of breast cancer now included for BRCA1/2 testing • For accounting for ancestry, other high-risk populations (in addition to Ashkenazi Jewish ancestry) included in the criteria for testing newly diagnosed patients • All individuals who are candidates for PARP inhibitor therapy are included in scope for testing • Family history criteria for testing related to having a relative with multiple primary breast cancers expanded to first- or second-degree relative • Family history criteria for testing related to having a relative with epithelial ovarian, fallopian tube, or primary peritoneal cancer expanded to include first-, second-, or third-degree relatives • Family history criteria for testing related to having a relative with breast cancer who is also an individual assigned male sex	

	at birth expanded to include first-, second-, or third-degree relatives • Family history criteria for testing related to having a relative age <50 with breast cancer expanded to be at least one relative who is a first- or second-degree blood relative • Clarified the statement about BRCA risk models, eliminating reference to tools that are not examples of validated risk models • Clarified that direct-to-consumer testing refers to those tests that are FDA approved; also clarified language to refer to pathogenic or likely pathogenic variants for consistency with other guideline criteria	

	Hereditary epithelial ovarian cancer	
Individuals with personal history of invasive epithelial ovarian carcinoma	**Individuals with personal history of invasive epithelial ovarian carcinoma** Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary f**or individuals with a personal history of invasive epithelial ovarian cancer (including fallopian tube cancer or primary peritoneal cancer) at any age to aid in therapy and surgical decision-making and/or for personal and family risk assessment. See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing. **Individuals with no current or prior diagnosis of epithelial ovarian carcinoma** Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary** for individuals without a current or prior diagnosis of epithelial ovarian cancer with personal or family history suggests the possibility of a pathogenic variant with **ANY** of the following: • At least one first- or second-degree blood relative with epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer at any age • Risk of a pathologic or likely pathologic variant in BRCA1 or BRCA2 is ≥5% based on a validated predictive model See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing. **Explanation of change** Clarified scope of epithelial ovarian cancer testing to include fallopian tube cancer and primary peritoneal cancer Removed use of common screening tools used for assessing who should be further evaluated for BRCA risk; specified that the criteria are focused on validated predictive models that indicate the risk of a pathologic or likely pathologic variant in BRCA1 or BRCA2 is ≥5%	March 23, 2025

	Hereditary pancreatic ductal adenocarcinoma	
	Individuals with personal history of exocrine pancreatic cancer (pancreatic ductal adenocarcinoma) Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary** for individuals with a personal history of invasive epithelial ovarian	March 23, 2025

	cancer at any age to aid in therapy and surgical decision-making and/or for personal and family risk assessment. See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing. **Individuals with no current or prior diagnosis of exocrine pancreatic cancer (pancreatic ductal adenocarcinoma)** Germline genetic testing using a multi-gene panel that includes BRCA1 and BRCA2 is considered **medically necessary** for individuals without a current or prior diagnosis of epithelial ovarian cancer with personal or family history suggests the possibility of a pathogenic variant with **ANY** of the following: • First-degree blood relative with exocrine pancreatic cancer (pancreatic ductal adenocarcinoma) • Risk of a pathologic or likely pathologic variant in BRCA1 or BRCA2 is ≥5% based on a validated predictive model. See multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma* for details about the scope of panel testing. **Explanation of change** Removed use of common screening tools used for assessing who should be further evaluated for BRCA risk; specified that the criteria are focused on validated predictive models that indicate the risk of a pathologic or likely pathologic variant in BRCA1 or BRCA2 is ≥5% Clarified scope of pancreatic cancer testing to include exocrine pancreatic cancer (pancreatic ductal adenocarcinoma)	

	Multi-gene panel testing for HBOP	
Multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma	***Multi-gene panel testing for hereditary breast, ovarian, or pancreatic carcinoma** Germline genetic testing which includes additional pathogenic variants (beyond BRCA1 or BRCA2) related to breast, ovarian, or pancreatic cancer 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 pathogenic or likely pathogenic germline variants associated with significantly increased risk for breast and/or associated cancers along with established management implications See Tables 1, 2, and 3 [not included here], for detailed examples of genes that should be tested based on the members' presentation related to one or more of breast, ovarian, and pancreatic cancers, respectively. *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.* **Explanation of change** Clarified in the HBOP multi-gene panel statement that the panel genes are related to known pathogenic or likely pathogenic	March 23, 2025

	germline variants and clarified that the genes in Tables 1, 2, and 3 refer to detailed examples of genes that should be tested based on the members presentation related to one or more o of these cancers (breast, ovarian, or pancreatic cancer) For pancreatic carcinoma, added CDK4 to the multi-gene panel list (in Table 3, not shown) For breast cancer, removed the following genes from the multi-gene panel list: ATM, BARD1, CHEK2, RAD51C, and RAD51D (in Table 1, not shown)	

	Melanoma	
Melanoma	Germline genetic testing of a focused set of 20 or fewer specific genes which may include CDKN2A, BAP1, and CDK4 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 with 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** Gene list expanded to include CDK4 pathogenic variants	March 23, 2025

	Nevoid basal cell carcinoma syndrome	

Nevoid basal cell carcinoma syndrome	(also called Gorlin-Goltz syndrome; basal cell nevus syndrome) Focused genetic testing that may include testing for PTCH variants (including associated downstream gene variants, such as SMO and genes such as SUFU) is 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.
	• **Major criteria**
	  ○ Multiple basal cell carcinomas (out of proportion to prior sun exposure and skin type) or a basal cell carcinoma diagnosed before age 30 (excluding basal cell carcinomas that develop after radiotherapy)
	  ○ Lamellar calcification of the falx cerebri
	  ○ Odontogenic keratocyst
		March 23, 2025

	○ Palmar or plantar pitting ○ First-degree relative with nevoid basal cell carcinoma syndrome • **Minor criteria** ○ Childhood medulloblastoma (primitive neuroectodermal tumor) ○ Lymphomesenteric or pleural cysts ○ Macrocephaly ○ Cleft lip or cleft palate ○ Vertebral or rib anomalies observed on x-ray ○ Preaxial or postaxial polydactyly ○ Ovarian or cardiac fibromas ○ Ocular anomalies (cataract, developmental defects, and pigmentary changes of the retinal epithelium) **Explanation of change** Clarified that SMO is a PTCH gene variant and SUFU is a gene The threshold for number of basal cell carcinomas is no longer set at 5 in a lifetime and may be as low as two (multiple) if this is considered out of proportion to prior skin exposure or skin type Removed reference to the individual's age for Lamellar calcification of the falx cerebri (major criterion) Minor clarifications in the wording of major and minor criteria to improve the clarity and simplicity of applying the criteria	

	Endocrine neoplasms	
Endocrine neoplasms	Germline genetic testing for a single gene or a panel focused on the set of genes reasonably needed to assess the suspected condition is considered **medically necessary** in individuals with a personal history of **ANY** of the following: • Adrenocortical carcinoma (ACC) • Paraganglioma or pheochromocytoma • Duodenal or pancreatic neuroendocrine tumor • Type 2 gastric neuroendocrine tumor • Gastrointestinal stroma tumors (GIST) diagnosed before age 30 • Medullary thyroid cancer • Parathyroid adenoma, diffuse hyperplasia, or primary hyperparathyroidism before age 30 • Multiple parathyroid adenomas or recurrent primary hyperparathyroidism • MEN2-related features including lip mucosal neuromas resulting in thick vermilion of the upper and lower lip, mucosal neuromas of the lips and tongue, medullated corneal nerve fibers, marfanoid habitus. • Family history of neuroendocrine tumors or associated conditions (including primary hyperparathyroidism, duodenal or pancreatic neuroendocrine tumor, pituitary adenoma, or carcinoid tumor of bronchial, thymic, or gastric origin) in a first-, second-, or third-degree relative and clinical features in the individual suspicious of a hereditary condition See Tables 4-7 below [not included here] for scope of genes that should be tested based on the underlying type of endocrine neoplasm.	March 23, 2025

	Explanation of change Added criteria for early onset GI stromal tumors (expansive) to account for evaluation for SDHB gene-deficient GIST Clarified that focused set of genes refers to up to 20 genes Clarified that the criteria related to duodenal or pancreatic gastrinomas is more generally described as neuroendocrine tumors of those organs Clarified that family history of neuroendocrine tumors refers to first-, second-, or third-degree relatives Provided some examples of associated conditions in the criteria about family history of neuroendocrine tumors or associated conditions Added tables to refer to scope of genes that should be tested (i.e., the lower limit) according to the endocrine neoplasm	

	Kidney cancer	

Kidney cancer	Germline genetic testing for a single gene OR a targeted panel (up to 20 genes) which may include BAP1, FH, FLCN, MET, SDHA, SDHAF2, SDHB, SDHC, SDHD, PTEN, or VHL is considered medically necessary for hereditary kidney cancer syndromes in individuals with **ANY** of the following:
	• Personal history of renal cell carcinoma diagnosed at age 46 or younger
	• Personal history of renal cell carcinoma and at least one first- or second-degree relative with renal cell carcinoma
	• Personal history of bilateral or multifocal renal tumors
	• Personal history of ANY of the following characteristics:
	  ○ Kidney tumor multifocal papillary histology
	  ○ Kidney tumor with Birt-Hogg-Dubé syndrome histology (multiple chromophobe, oncocytoma, or oncocytic hybrid)
	  ○ Hereditary leiomyomatosis-associated renal cell carcinoma (HLRCC)
	  ○ Renal cell carcinoma with fumarate hydratase deficiency or succinate hydrase deficiency
	  ○ Angiomyolipomas of the kidney and one additional tuberous sclerosis complex criterion in the same individual
	• Unaffected individual with a family history of renal cell carcinoma in two or more first- or second-degree relatives
	
	Explanation of change
	Expanded criteria to include individuals with a personal history of various rare kidney tumors (Birt-Hogge-Dubé syndrome, HLRCC associated renal cell carcinoma, etc.)
	Expanded criteria to include unaffected individuals with two or more first- or second-degree relatives with renal cell carcinoma
	Listed specific genes for multi-gene panel testing
		March 23, 2025

	Prostate Cancer	
Prostate Cancer	Germline genetic testing of a focused set of 20 or fewer specific genes which may include BRCA2, BRCA1, ATM, HOXB13, 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:	March 23, 2025

	• Personal history of **ANY** of the following:
	  ○ Metastatic, locally advanced, or high/very high risk localized prostate cancer
	  ○ Prostate cancer diagnosed before age 60 **AND** at least one first-degree relative with prostate cancer diagnosed before age 60
	  ○ Low- or intermediate-risk localized prostate cancer concomitant with **ANY** of the following:
	  ▪ A personal history of breast, pancreatic, gastric, brain, melanoma, intestinal (colorectal or small bowel), or upper tract urothelial cancer(s)
	  ▪ A family history of breast cancer in relatives assigned female sex at birth and diagnosed at or before age 50
	  ▪ A family history of pancreatic, gastric, brain, melanoma, intestinal cancer (colorectal or small bowel), or endometrial cancer diagnosed at or before age 50
	  ▪ A family history of upper tract urothelial cancer(s) in first- or second-degree relatives
	  ▪ Ashkenazi Jewish ancestry
	  ▪ Intraductal or cribriform histology
	
	Explanation of change
	For individuals with low-risk prostate cancer, criteria expanded to include family history of breast cancer in relatives assigned female at birth and age ≤50; family history of pancreatic, gastric, brain, melanoma, intestinal (colorectal or small bowel), or endometrial cancer diagnosed at age ≤50; family history of upper tract urothelial cancer(s) in first- or second-degree relatives; Ashkenazi Jewish ancestry; intraductal or cribriform histology
	For individuals with intermediate risk prostate cancer, criteria expanded to include family history of breast cancer in relatives assigned female at birth and age ≤50; family history of pancreatic, gastric, brain, melanoma, intestinal (colorectal or small bowel), or endometrial cancer diagnosed at age ≤50; family history of upper tract urothelial cancer(s) in first- or second-degree relatives
	Removed CHEK2 or PALB2 from the multi-panel gene list for prostate cancer	

Prostate Cancer	• Family history suggests the possibility of a pathogenic variant related to increased risk of prostate cancer with **ANY** of the following:
	  ○ Two or more first-degree relatives with prostate cancer
	  ○ One or more first- or second-degree relatives with prostate cancer diagnosed before age 60 or who died of prostate cancer
	  ○ Risk of a pathologic or likely pathologic variant in BRCA1 or BRCA2 is ≥5% based on a validated predictive model
	  ○ At least one first-, second-, or third-degree blood relative with breast cancer diagnosed at or before age 50
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	○ At least one first-, second-, or third-degree blood relative with epithelial ovarian, fallopian tube, or primary peritoneal cancer ○ At least one first-degree, second-, or third-degree blood relative with multiple primary breast cancers (metachronous or synchronous) ○ At least one first-, second-, or third-degree blood relative on the same side of the family with breast cancer in an individual assigned male sex at birth ○ At least one first-, second-, or third-degree blood relative on the same side of the family with metastatic prostate cancer, or high or very high-risk grade group of localized or locally advanced prostate cancer ○ Three or more first-, second-, or third-degree blood relatives on the same side of the family with invasive breast and/or prostate cancer ○ Individuals with at least two first-degree blood relatives with pancreatic cancer ○ Ashkenazi Jewish descent **AND** at least one first-degree blood relative with breast cancer ○ Ashkenazi Jewish descent **AND** two or more second-degree blood relatives on the same side of the family with breast or epithelial ovarian cancer ○ Individuals requiring confirmatory testing of a specific gene or genes found to have pathogenic variants involving BRCA2, BRCA1, CHEK2, ATM, PALB2, HOXB13, MLH1, MSH2, MSH6, PMS2, or EPCAM from ANY of the following: ▪ 23andMe PGS (or similar FDA approved commercial direct-to-consumer testing) ▪ In the context of somatic testing for malignancy ▪ Findings discovered in the context of IRB approved clinical research **Explanation of change** Expanded criteria to first-, second-, or third-degree relatives with multiple primary breast cancers Expanded criteria for personal history of prostate cancer diagnosed before age 60 to include at least one first- or second-degree relative For individuals unaffected by prostate cancer, criteria are expanded to include family history indicators for risk of BRCA 1 or BRCA2 pathogenic variants that match the hereditary breast, ovarian, or pancreatic (HBOP) criteria based on family history Noted that confirmatory testing from direct-to-consumer or research study findings is limited to testing of the specific genes with pathogenic mutations. Also clarified that the direct-to-consumer testing is FDA approved. Removed use of common screening tools used for assessing who should be further evaluated for BRCA risk; specified that the criteria are focused on validated predictive models that indicate the risk of a pathologic or likely pathologic variant in BRCA1 or BRCA2 is ≥5%	

	Carrier Screening in the Reproductive Setting	

Description and Scope	Genetic carrier screening in the reproductive setting applies to individuals in the preconception setting, individuals who are currently pregnant, and reproductive partners of individuals who are currently pregnant. These tests are performed on asymptomatic individuals to identify future pregnancies or current pregnancies that are at increased risk for autosomal recessive or X-linked single gene disorders. This testing is generally performed on individuals who have not been diagnosed with, and do not show clinical characteristics of, the condition being evaluated. **Explanation of change** Clarified that these tests are performed on asymptomatic individuals to identify future pregnancies or current pregnancies that are at increased risk for autosomal recessive or X-linked single gene disorders	March 23, 2025

	Standard carrier screening	
Cystic fibrosis and spinal muscular atrophy	**Cystic fibrosis and spinal muscular atrophy** Standard screening for cystic fibrosis (CFTR testing) and spinal muscular atrophy (SMN1 testing) using accepted gene variant sets is considered **medically necessary** in the following scenarios: • All pregnant individuals • An individual considering pregnancy **Explanation of change** Removed CBC from the list of acceptable prior testing Removed "AND their reproductive partner" for clarity	March 23, 2025

	Expanded carrier screening	

	Multigene 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, among others) known to be at increased risk for certain conditions, other than cystic fibrosis, spinal muscular atrophy, and hemoglobinopathies
	  ○ One or both individuals do not have access to a biological family history due to reasons such as adoption or use of a reproductive donor as documented in the member's medical record
	  ○ The individual and their reproductive partner are known or suspected to be consanguineous as documented in the member's medical record
	• The conditions on the multigene panel have at least a 1 in 100 carrier frequency*
	• 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
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	• Knowledge of the pathogenic variant(s) may be used for management of either the pregnancy or the potentially affected fetus or child, or for family planning ***Note:** Conditions on multigene panels can have carrier frequencies less than 1 in 100 for a consanguineous partnership.* **Explanation of change** Slightly modified the scope of ancestry examples to simplify Clarified that adoption or consanguinity are factors taken into account when documented in the member's medical record Emphasized the 1 in 100 carrier frequency for readability. For individuals in a consanguineous partnership, allow for conditions on multigene panels with less than 1 in 100 carrier frequencies. Removed criteria stating that alternate biochemical tests are not available, have provided an indeterminate result, or are less accurate than genetic testing	

	Exclusions	
Exclusions	The following tests and clinical scenarios are considered **not medically necessary**: • Carrier screening for autosomal dominant conditions • Carrier screening for conditions known to have adult-onset • 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** Explicitly state that autosomal dominant conditions are excluded from carrier screening (clarification) Parenthetical mention of conditions known to have adult onset were removed	March 23, 2025

	Carrier testing based on family history	
Carrier testing based on family history	Condition-specific carrier testing is considered medically necessary when ANY of the following criteria are met: • The individual has a previously affected child with the genetic condition being evaluated • Either partner has a first-, second-, or third-degree relative who is affected with 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** Clarification	March 23, 2025

	Genetic Testing for Inherited Conditions	

	General requirements – Genetic testing for inherited conditions	
Genetic Testing for Inherited Conditions	Confirmatory genetic testing of the identified variant(s) is considered **medically necessary** if **ALL** of the criteria above [not included here] are met and **EITHER** of the following apply: • An individual identified to have a pathogenic or likely pathogenic germline variant in genes with established clinical utility based on FDA approved direct-to-consumer genetic testing • An individual identified to have a pathogenic or likely pathogenic germline variant in genes with established clinical utility based on results of IRB approved clinical research studies **Testing may be performed only once per lifetime for a given condition.** **Explanation of change** Added confirmatory genetic testing (expansive) for individuals identified to have a pathogenic or likely pathogenic germline variant in genes with established clinical utility based on results of IRB approved clinical research studies Clarified for testing based on FDA approved direct-to-consumer genetic testing that testing is also for an individual identified to have a pathogenic or likely pathogenic germline variant in genes with established clinical utility	March 23, 2025

	Cardiac conditions	
Hereditary cardio-myopathy syndromes	**Hereditary cardiomyopathy syndromes** Genetic testing for pathogenic variants associated with hereditary hypertrophic cardiomyopathy (HCM), arrhythmogenic right ventricular cardiomyopathy/dysplasia (ARVC/D), or inherited dilated cardiomyopathy (DCM) is considered medically necessary when ALL of the following criteria are met: • The individual to be tested has a first-degree relative with supporting clinical features of one of the above-named inherited cardiomyopathy syndromes (HCM, ARVC/D, DCM) • The individual to be tested has been clinically screened to exclude an alternate, acquired etiology of cardiomyopathy (e.g., ischemic cardiomyopathy, cardiac amyloidosis, etc.) • The genetic testing is focused on pathogenic variants relevant to the individual's suspected clinical diagnosis and known familial genetics **OR** • For clinically symptomatic individuals under the age of 18 for whom there is no known family history, a genetic syndrome has not been identified via clinical diagnosis, and an alternate, acquired etiology of cardiomyopathy (e.g., ischemic cardiomyopathy, cardiac amyloidosis, etc.) has been excluded **Explanation of change** New criteria for genetic testing in a pediatric population (expansive)	March 23, 2025

	Hereditary aortopathies	
	Hereditary aortopathies	March 23, 2025

	Targeted genetic testing for pathogenic variants associated with significantly increased risk for heritable thoracic aortic disease (HTAD) may be **medically necessary** when **ANY** of the following are met: • The individual to be tested has a personal history of TAD before age 60 AND other causes of acquired cardiac disease have been excluded • The individual to be tested has a personal history of TAD at any age AND an additional personal history of aneurysm AND/OR dissection/rupture of other arteries • The individual to be tested has other physical findings consistent with a syndromic connective tissue disorder in which an increased genetic risk for TAD is known but the underlying diagnosis cannot be established. (Examples include, but are not limited to, Marfan syndrome, Loeys-Dietz syndrome, vascular Ehlers-Danlos syndrome, or smooth muscle dysfunction syndrome) • The individual to be tested is currently asymptomatic but has one or more first- or second-degree blood relative(s) who are unavailable for genetic testing but had a history of TAD, unexplained sudden cardiac death, and/or aneurysms/dissections in other arteries Genetic testing for a known pathogenic variant in a gene associated with increased genetic risk for aortopathy is medically necessary when ALL of the following are met: • The individual has a first- or second-degree blood relative who has a pathogenic variant associated with HTAD • The testing is targeted to the gene of the known familial pathogenic or likely pathogenic variant **Explanation of change** New medical necessity criteria for hereditary aortopathies (expansive)	

	Post-mortem testing after sudden cardiac death	
Post-mortem testing after sudden cardiac death	**Post-mortem testing after sudden cardiac death** After sudden cardiac death, genetic testing for pathogenic variants associated with cardiac channelopathies is considered **medically necessary** on an asymptomatic individual when ALL of the following criteria are met: • The decedent was a first- or second-degree relative of the individual requesting the test • Sudden cardiac death occurred at or before age 50 • The cause of sudden cardiac death remains unexplained despite the clinical history and autopsy, toxicology, and cardiac pathology findings **Explanation of change** Clarifications	March 23, 2025

	Neurological conditions	
Neurological conditions	Genetic testing for treatment of pathogenic variants associated with inherited neurological conditions may be **medically necessary**	March 23, 2025

	when the general requirements OR multi-gene panel criteria listed above [not included here] 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) Single gene testing for SOD1 pathogenic variants is considered medically necessary when **BOTH** of the following criteria are met: • The individual is an adult with a clinical diagnosis of amyotrophic lateral sclerosis (ALS) • The individual is a candidate for treatment with tofersen (Qalsody) per the FDA label *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 Carelon Guidelines for Pharmacogenomic Testing.* **Explanation of change** Expanded criteria to include the new FDA approved Qalsody (tofersen) to treat patients with amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase 1 (SOD1) gene (SOD1-ALS)	

	Thrombophilia testing	

Thrombophilia testing	Thrombophilia genetic 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:
	• An individual who had a venous thromboembolism (VTE) at or before age 50 in association with unprovoking OR weakly provoking factors
	• An individual with recurrent VTE
	• An individual with VTE **AND EITHER** of the following:
	  ○ Two or more family members with a history of VTE
	  ○ One first-degree relative with VTE at or before age 40
	• An individual with VTE involving the cerebral or splanchnic veins
	• An individual contemplating pregnancy who has a first-degree relative with VTE AND a confirmed hereditary thrombophilia
	• An individual with an unprovoked VTE who is planning to stop anticoagulation. Test for thrombophilia if test results would change this decision.
	
	Not Medically Necessary:
	MTHFR-gene variant testing for hereditary thrombophilia risk assessment is considered **not medically necessary.**
	
	Explanation of change
		March 23, 2025

	Criteria in first bullet separated into multiple bullets for clarity. Aligned phrasing of criteria for consistency (i.e., An individual…). Specified the definition of "strong family history" for clarity (bullet 3). Changed "known" to "confirmed" for clarity (bullet 5). Removed restriction of low bleeding risk (bullet 6). Removed criterion in last bullet referring to contemplation of estrogen use with a first degree relative with VTE and a known hereditary thrombophilia test for that thrombophilia	

Radiation Oncology 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 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 (excludes Proton) **Special Treatment Procedure and Special Physics Consult**	
Radiation Therapy (excludes Proton)	**Special treatment procedure is indicated when extra planning time and effort is documented for ANY of the following:** • Cytotoxic chemotherapy and/or targeted therapy and/or immunotherapy within 90 days of RT • Brachytherapy when combined with external radiation therapy • Proton therapy • Total body or hemibody radiation • Pediatric patient requiring daily anesthesia and daily physician supervision during treatment • Certain cases requiring reconstruction of previous radiation plan, complex planning, and physics input • Stereotactic body radiation therapy (SBRT) in a complex medical setting (e.g..treating a patient on a ventilator) ○ Special treatment procedure is NOT medically necessary for uncomplicated SBRT treatment (such as for a single bone metastasis) • Other (documentation of special circumstances or time-consuming plan required) **Explanation of change** Limited the scenarios where special treatment procedure is indicated, to more closely align with recent ASTRO guidance.	March 23, 2025

	Breast Cancer	
Breast Cancer	• **Accelerated partial breast irradiation (APBI) is appropriate only for individuals who meet ALL of the following criteria:**	March 23, 2025

	○ Age 40 or greater for invasive disease or greater than 50 for DCIS ○ Tumor less than or equal to 2 cm with pathologically negative surgical margins ○ Lymph nodes are negative or show only immunohistochemical involvement, N0 or N0(i+) ○ Distance between the edge of the applicator and the skin is at least 6 mm **Explanation of change** Reduced the minimum age at which patients with invasive disease meet criteria for accelerated partial breast irradiation (APBI).	

	Head and Neck Cancers (including Thyroid)	
Head and neck	**Head and neck** Intensity Modulated Radiation Therapy (IMRT) is appropriate for head and neck cancers when **ANY** of the following conditions are met: • Glottic cancer, stage III and IV • Other advanced head and neck cancers • Lymphomas of the head and neck region • To treat a previously irradiated field Stereotactic Body Radiation Therapy (SBRT) is appropriate for head and neck cancer when the following condition is met: • Only to treat a previously irradiated field Brachytherapy is appropriate for head and neck cancer when the following condition is met: • To treat cancers including cancers of the lip, oral cavity, tongue (particularly base of tongue), tonsils, sinuses, nasopharynx, pharynx, and other neck cancers **Exclusions** Indications other than those addressed in this guideline are considered not medically necessary including, but not limited to: • Neutron therapy **Explanation of change** Removed indication for neutron therapy as this is no longer routinely used.	March 23, 2025

	Lung Cancer: Small Cell and Non-Small Cell	
Primary Lung Cancers Non-small cell lung cancer	**Primary Lung Cancers** **Non-small cell lung cancer** Stereotactic Body Radiation Therapy (SBRT) is appropriate for non-small cell lung cancer when **ANY** of the following conditions are met: • As an alternative to surgical resection when (**ALL must apply**) ○ Treatment intent is cure ▪ There is no evidence of nodal or distant metastases based on conventional staging techniques (Stage IA, IB, or IIA with negative lymph nodes) ○ Single lesion measuring less than or equal to 5 cm ○ Lesion is inoperable for **EITHER** of the following reasons:	March 23, 2025

	▪ Tumor location ▪ Individual is not a surgical candidate ▪ To treat a previously irradiated field The maximum number of fractions that is medically necessary for SBRT is 5. **Small cell lung cancer** Stereotactic Body Radiation Therapy (SBRT) is appropriate for small cell lung cancer when **ANY** of the following conditions are met: • As an alternative to surgical resection when (**ALL must apply**) ○ Treatment intent is cure ▪ There is no evidence of nodal or distant metastases based on conventional staging techniques (Stage IA, IB, or IIA with negative lymph nodes) ○ Single lesion measuring less than or equal to 5 cm ○ Lesion is inoperable for **EITHER** of the following reasons: ▪ Tumor location ▪ Individual is not a surgical candidate ▪ To treat a previously irradiated field The maximum number of fractions that is medically necessary for SBRT is 5. **Explanation of change** Clarified that the maximum number of fractions for SBRT is 5 in both NSCLC and SCLC	

	Oligometastatic Extracranial Disease	
Oligometastatic Extracranial Disease	**Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for extracranial oligometastatic disease when ALL of the following conditions are met:** • One (1) to three (3) metastatic lesions involving the lungs, liver, adrenal glands, or bone • Primary tumor is breast, colorectal, melanoma, non-small cell lung, prostate, renal cell, or sarcoma • Primary tumor is controlled • No prior history of metastatic disease For oligoprogressive disease, SBRT is approved for 1-3 lesions if there has been prior control with systemic therapy. **Explanation of change** Added scenario for oligoprogressive extracranial disease	March 23, 2025

	Other Tumor Types: Sarcoma, Thymoma and Thymic Carcinoma, Pediatric Tumors, and Other Malignancies	
Other Tumor Types: Sarcoma, Thymoma and Thymic Carcinoma, Pediatric	**Pediatric individuals (age 20 years or younger)** Intensity Modulated Radiation Therapy (IMRT), Stereotactic Radiosurgery (SRS), or Stereotactic Body Radiation Therapy (SBRT) is appropriate for pediatric patients when the following condition is met:	March 23, 2025

Tumors, and Other Malignancies	• To treat pediatric individuals (age 20 years or younger) with a radiosensitive tumor **Explanation of change** Combined criteria for IMRT, SRS, and SBRT Expanded criteria for SRS and SBRT to include any radiosensitive tumor	

	Prostate Cancer	
Prostate Cancer	**Fractionation** **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 28 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 32 fractions of EBRT/IMRT are considered medically necessary as adjuvant treatment to the prostate bed after prostatectomy. Up to 37 fractions of EBRT/IMRT are considered medically necessary for salvage treatment after prostatectomy. **Explanation of change** Modified number of fractions indicated, due to larger dose given in each individual fraction (no change in total dose to be given). Added scenario for salvage treatment after prostatectomy Also added max fraction number for salvage RT	March 23, 2025

	Perirectal Hydrogel Spacer for Prostate Radiotherapy	
Perirectal Hydrogel Spacer for Prostate Radiotherapy	**The use of an implanted hydrogel spacer between the prostate and rectum is medically necessary when primary definitive radiation therapy will be used to treat prostate cancer using** any form of external beam radiation therapy (3D conformal, IMRT, SBRT) **Explanation of change** Expanded the use of hydrogel spacers to include them in patients receiving any form of external beam radiation therapy	March 23, 2025

	Proton Beam Therapy	
Proton Beam Therapy	This guideline outlines different applications of proton beam therapy in the treatment of malignant and benign tumors and arteriovenous malformations.	March 23, 2025

	For all PBT requests outside of approved criteria, case control plan comparison is insufficient justification for PBT. A direct isodose comparison for an IMRT plan specific to the patient request is mandatory for consideration. **Explanation of change** Added clarifying statement that case control plan comparison is insufficient and that direct IMRT isodose comparison is required	

	Therapeutic Radiopharmaceuticals	
Pheochromo-cytoma and Paraganglioma	**Pheochromocytoma and Paraganglioma** 131I iobenguane (Azedra®) is no longer produced or distributed. **Explanation of change** Removed criteria for the use of Azedra since it is no longer produced or distributed	March 23, 2025

New 2024 Category III CPT Codes

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

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

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

Definitions

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

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

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

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