MASSACHUSETTS

MEDICAL POLICY ANNOUNCEMENTS

Posted August 2023

This document announces new medical policy changes that take effect November 1, 2023. Changes affect these specialties:

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

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	November 1, 2023	Commercial	PA is still not required.

		and flaps to medically necessary statement.			

NEUROLOGY ORTHOPEDICS REHABILITATION

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Minimally Invasive Ablation Procedures for Morton and Other Peripheral Neuromas	719	Policy statements **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.	August 1, 2023	Commercial	No action 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	November 1, 2023	Commercial Medicare	No action required.

		investigational for cancer screening.			

PLASTIC SURGERY ONCOLOGY

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

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	Prior authorization is still required.

				Managed Blue for Seniors with Custom BCBSMA Formulary	

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:	November 5, 2023

	○ 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 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	November 5, 2023

	• 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 **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;	November 5, 2023

	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 ○ 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	**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	November 5, 2023

	• 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 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.
	
	<u>Cancer-specific Criteria</u>
	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.	

New 2023 Category III CPT Codes

All category III CPT Codes, including new 2023 codes, are **non-covered** unless they are explicitly described as "medically necessary" in a BCBSMA medical policy. To search for a particular code, click the following link: https://www.bluecrossma.org/medical-policies/ and type the code in the search box on the page. Consult the coverage statement of any associated medical policy. ***If there is no associated policy, the code is non-covered*.**

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

Definitions

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

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

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

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

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