MASSACHUSETTS

MEDICAL POLICY ANNOUNCEMENTS

Posted February 2024

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

Gastroenterology
Neurology
Plastic Surgery

Carelon Clinical Appropriateness Guidelines
Genetic Testing

- Hereditary Cancer
- Carrier Screening in the Reproductive Setting (Previously in the Prenatal Setting and Preimplantation Genetic Testing
- Genetic Testing for Inherited Conditions

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

GASTROENTEROLOGY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Medical and Surgical Management of Obesity including Anorexiants	379	**Policy revised** to include: Bariatric Surgery in Adolescents (ages 12-18, who may not yet have completed bone growth) is considered **medically necessary** according to similar weight-based criteria used for adults. **Bariatric Surgery Selection Criteria clarified** to include: The individual has a BMI >30kg/m2 and has type 2 diabetes. **One anastomosis gastric bypass** added under investigational bariatric surgical procedures for the treatment of class III (BMI >40 kg/m^2 or >35	May 1, 2024	Commercial	Prior authorization is still required for surgical services.

		kg/m^2 with any of the comorbidities listed) obesity in adults who have failed weight loss by conservative measures.			

NEUROLOGY

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

PLASTIC SURGERY

POLICY TITLE	POLICY NO.	POLICY CHANGE SUMMARY	EFFECTIVE DATE	PRODUCTS AFFECTED	PROVIDER ACTIONS REQUIRED
Treatment of Varicose Veins/Venous Insufficiency	238	**Policy revised** to include the following medically necessary statement under *Symptomatic Varicose Tributaries:* Treatments of the tributary veins are considered medically necessary if saphenous reflux is not present or already successfully eliminated, the veins are > than 4 mm in diameter and if the individual remains symptomatic after a six-week trial of conservative therapy.	May 1, 2024	Commercial	Prior authorization is still required.
Suction Lipectomy for Lipedema	043	**New medical policy** describing ongoing medically necessary indications. Medically necessary criteria will be added. Related policies:	May 1, 2024	Commercial Medicare	Prior authorization is still required.

		▪ MP 068 Plastic Surgery ▪ MP 037 Surgical and Debulking Treatments for Lymphedema			

Carelon Clinical Appropriateness Guidelines

Genetic Testing Guidelines

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

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

Carelon Guideline	Policy Change Summary	Effective Date
	Hereditary Cancer	
Hereditary Cancer	**Genetic Counseling** Counseling is strongly recommended prior to hereditary cancer screening that involves genetic testing and should include **ALL** of the following components: • Interpretation of family and medical histories to provide a risk assessment for disease occurrence or recurrence • Education about inheritance, genetic testing, disease management, prevention, risk reduction, and resources • Counseling to promote informed choices and adaptation to the risk or presence of a genetic condition • Counseling for the psychological aspects of genetic testing • Counseling should include the following details: o Limitations of the testing used o A negative result does not indicate heritable risk is zero or low o Identification of inconclusive results called variants of uncertain significance is possible. o Modifications to genetic variants' pathogenicity interpretations can occur and patients may be recontacted with reclassified results in the future *Note: Post-test counseling should be performed for any diagnostic genetic test result.* **Explanation of change:** Clarification	June 30 2024
Hereditary Cancer	**Serrated polyposis syndrome (SPS)** Genetic testing for serrated polyposis syndrome (SPS) is considered not medically necessary for any indication.	June 30 2024

	Explanation of change: Clarification on exclusion statement that previously appeared in the rationale for Hamartomatous polyposis syndromes. Now appears as its own section.	
Hereditary Cancer	**Hereditary mixed polyposis syndrome (GREM1-associated mixed polyposis)** Genetic testing for hereditary mixed polyposis syndrome, to include the GREM1 variant OR any other genes, is considered not medically necessary for any indication. **Explanation of change:** Clarification on exclusion statement that previously appeared in the rationale for Hamartomatous polyposis syndromes. Now appears as its own section.	June 30 2024

Hereditary Cancer	**Li-Fraumeni syndrome**
	Testing for pathogenic or likely pathogenic variants of TP53 is considered medically necessary for individuals at risk based on ANY of the following (per the Chompret criteria, updated in 2015):
	• Breast cancer diagnosed at age 30 or younger
	• Breast cancer diagnosed at age 45 or younger and EITHER of the following:
	  ○ At least one first- or second-degree relative with a Li-Fraumeni syndrome spectrum tumor other than breast diagnosed before age 56
	  ○ At least one first- or second-degree relative with multiple primary cancers at any age
	• Personal history of a Li-Fraumeni syndrome spectrum tumor other than breast cancer (soft tissue sarcoma, osteosarcoma, CNS tumor) diagnosed at age 45 or younger and EITHER of the following:
	  ○ At least one first- or second-degree relative with a Li-Fraumeni syndrome spectrum tumor before age 56
	  ○ At least one first- or second-degree relative with multiple primary cancers at any age
	• Personal history of multiple tumors (other than multiple tumors of the breast), of which two belong to the Li-Fraumeni syndrome spectrum AND at least one was diagnosed at age 45 or younger
	• Personal history of adrenocortical carcinoma, choroid plexus carcinoma, or embryonal anaplastic rhabdomyosarcoma
	• Patient who has had a pathogenic or likely pathogenic variant of TP53 identified on tumor genomic testing
	• Individuals with at least one first-, second-, or third-degree relative with a known TP53 variant
	Explanation of change: Expand indication to include individuals with at least one first-, second-, or third-degree relative with a known TP53 variant.
		June 30 2024

Hereditary Cancer	**Hereditary breast, ovarian, and pancreatic cancer (HBOP)** **BRCA1 and BRCA2** Germline genetic testing for known familial pathogenic variants of BRCA1 or BRCA2 is considered medically necessary in the following scenarios: • Any first-, second-, or third-degree relative who has a known BRCA1 or BRCA2 pathogenic variant, where the results will influence reproductive decision-making or decision-making about cancer screening	June 30 2024

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

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

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

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

	Explanation of change: Expand multi-gene panel testing to include ovarian and pancreatic cancer. Expansive regarding the gene lists which now include the following: BARD1, RAD51C, and RAD51D for breast carcinoma; ATM, BRCA1, BRCA2, BRIP1, MLH1, MSH2, MSH6, PMS2, EPCAM, PALB2, RAD51C, and RAD51D for epithelial ovarian cancer; and ATM, BRCA1, BRCA2, CDK2NA, MLH1, MSH2, MSH6, PMS2, EPCAM, PALB2, STK11, and TP53 for pancreatic adenocarcinoma) as detailed in revised/additional tables.	
Hereditary Cancer	**Melanoma** Testing for CDKN2A and/or BAP1 pathogenic variants are considered medically necessary for persons at risk for familial melanoma, familial atypical multiple mole melanoma-pancreatic cancer syndromes, or familial atypical multiple mole melanoma syndrome (FAMMM) as defined by ANY of the following diagnostic criteria: • Personal history of three (3) or more melanomas • Personal history of melanoma and pancreatic cancer (exocrine-type) • Personal history of melanoma and a personal or family history in two or more first-degree relatives of mesothelioma or clear cell renal carcinoma or basal cell carcinoma (BAP-1 associated cancers) • Personal history of melanoma and astrocytoma • Three or more first- or second-degree relatives with melanoma or pancreatic cancer • Personal history of invasive cutaneous melanoma who have a first-degree relative diagnosed with pancreatic cancer (exocrine-type) • Both melanoma and astrocytoma in two or more first-degree relatives **Explanation of change:** Expansive, to align with NCCN. Also, clarification changes.	June 30 2024
Hereditary Cancer	**Nevoid basal cell carcinoma syndrome** Focused genetic testing that may include testing for PTCH variants (including associated downstream variants, such as SMO and SUFU) are considered medically necessary for persons at risk for nevoid basal cell carcinoma syndrome based on the following diagnostic criteria. The individual must meet ANY of the following: TWO (2) major criteria, ONE major criterion AND two minor criteria, OR THREE (3) minor criteria. [No changes to Major criteria and Minor criteria] **Explanation of change:** Clarified downstream variants.	June 30 2024
Hereditary Cancer	**Kidney cancer** Germline genetic testing for a single gene OR a targeted panel is considered medically necessary for hereditary kidney cancer syndromes in individuals with a personal history of ANY of the following: • Renal cell carcinoma diagnosed at age 46 or younger • Bilateral or multifocal renal tumors • At least one first- or second-degree relative with renal cell carcinoma	June 30 2024

	Explanation of change: Clarification only. Table (not shown here) added to the Rationale with examples of variants, prevalence, and renal cell carcinoma risk listed by condition.	

Hereditary Cancer	**Prostate cancer**
	(Also see Lynch syndrome and HBOP)
	Germline genetic testing of a focused set of 20 or fewer specific genes which may include HOXB13, BRCA2, BRCA1, CHEK2, PALB2, ATM, MLH1, MSH2, MSH6, PMS2, and EPCAM to inform assessment of hereditary risk of prostate cancer is considered medically necessary for individuals with a history of ANY of the following:
	• Personal history of ANY of the following:
	  ○ Metastatic, locally advanced, or high/very-high risk localized prostate cancer
	  ○ Intermediate risk prostate cancer with intraductal or cribriform histology or Ashkenazi descent by family history
	  ○ Prostate cancer diagnosed before age 60 AND at least one first-degree relative with prostate cancer diagnosed before age 60
	  ○ One or more pathogenic variants found by tumor somatic testing of ANY of the following genes:
	  ▪ BRCA2, BRCA1, CHEK2, ATM, PALB2, MLH1, MSH2, MSH6, PMS2, or EPCAM
	  ○ Low or intermediate risk localized prostate cancer concomitant with a personal history of breast, pancreatic, melanoma, intestinal (colorectal or small bowel), or upper tract urothelial cancer(s)
	• Family history of ANY of the following:
	  ○ Two or more first-degree relatives with prostate cancer
	  ○ One or more first-degree relatives with prostate cancer diagnosed before age 60 or who died of prostate cancer
	Explanation of change: Expansive regarding the gene list (which now adds up to 20 genes and includes PALB2, MLH1, MSH2, MSH6, PMS2, and EPCAM), and the gene list for those pathogenic variants found by somatic tumor testing. Expansive for circumstances where intermediate risk and where low- or intermediate-risk localized prostate cancer are now considered medically necessary. Clarifications and reorganization.
		June 30 2024

Carrier Screening in the Reproductive Setting (Previously in the Prenatal Setting and Preimplantation Genetic Testing		
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplan-tation Genetic Testing**	**Genetic counseling** The approach chosen for any reproductive carrier screening program should involve shared decision-making between the patient and the clinician. Counseling is encouraged prior to any reproductive carrier screening that involves genetic testing and should include ALL of the following components: • Interpretation of family and medical histories to provide a risk assessment for disease occurrence or recurrence • Education about inheritance patterns, disease severity of conditions being screened for, and the potential need for prenatal diagnosis for confirmation of an affected fetus should the couple be found to be both carriers of the same condition • Counseling to promote informed choices and adaptation to the risk or presence of a genetic condition	June 30 2024

	• Counseling for the psychological aspects of genetic testing
	• Counseling for carrier screening should include the following details:
	  ○ Positive/carrier results are common and will not usually have an impact on one's own health
	  ○ Carrier screening of the individual's partner is recommended if the individual is found to be a carrier of an autosomal recessive condition
	  ○ Carrier screening may rarely uncover incidental findings, such as a possible diagnosis and/or personal health risks
	  ○ A negative result reduces, but does not eliminate carrier risk
	Note: Post-test counseling should be performed for any at-risk individuals/couples.
	Explanation of change: Clarifications	

Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplantation Genetic Testing**	**Standard carrier screening** Standard screening for cystic fibrosis (CFTR testing) and spinal muscular atrophy (SMN1 testing) using accepted gene variant sets is considered medically necessary for all pregnant individuals or an individual considering pregnancy and their reproductive partners. Standard screening for hemoglobinopathies (HBA1/HBA2 and HBB testing) using hemoglobin electrophoresis or molecular genetic testing is considered medically necessary in the following scenarios IF no prior testing results (CBC, hemoglobin electrophoresis and/or HBA1/HBA2 and HBB gene analysis) are available for interpretation: • All pregnant individuals • An individual considering pregnancy AND their reproductive partner **Explanation of change:** Expansive to include standard hemoglobinopathy screening for all pregnant individuals or an individual considering pregnancy. Clarifications.	June 30 2024
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplantation Genetic Testing**	**Condition specific carrier testing based on family history** Targeted carrier testing is considered medically necessary when ANY of the following criteria are met: • The individual has a previously affected child with the genetic condition being evaluated • Either partner has a first-, second-, or third-degree relative who is affected with the genetic condition being evaluated • The reproductive partner of the individual being tested has a pathogenic variant in the gene associated with the condition being evaluated **Explanation of change:** Clarifications	June 30 2024
Carrier Screening in the Reproductive Setting **(Previously in the**	**Expanded carrier screening*** Expanded carrier screening (i.e., multigene testing) is considered medically necessary when ALL of the following criteria are met: • ONE or more of the following apply: ○ One or both individuals have ancestry (e.g., Ashkenazi Jewish, Finnish, French Canadian, Mediterranean, Southeast Asian, among others) known to be at increased risk for certain conditions, other than cystic fibrosis, spinal	June 30 2024

Prenatal Setting and Preimplan-tation Genetic Testing	muscular atrophy, and hemoglobinopathies (e.g., conditions that have a carrier frequency of at least 1 in 100 in that ancestry) ○ The individual and their reproductive partner are known or suspected to be consanguineous ○ One or both individuals do not have access to a biological family history due to reasons such as adoption or use of a reproductive donor • The genes included on the panel are consistent with the above bullet point reason for testing • The genetic disorders being evaluated have gene disease clinical validity AND pathogenic variants in the genes are associated with significant morbidity and/or mortality in affected individuals • The test has sufficiently high sensitivity and specificity to guide clinical decision making • Alternate biochemical or other clinical tests are not available, have provided an indeterminate result, or are less accurate than genetic testing • Knowledge of the pathogenic variant(s) may be used for management of either the pregnancy or the potentially affected fetus or child, or for family planning *Note: Expanded carrier screening should target genes that are associated with family history and ancestry. Additionally, genes included in the panel should be shown to impact patient management and health outcomes. **Explanation of change:** Clarifications	
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplan-tation Genetic Testing**	**Preimplantation genetic testing** Criteria moved to Genetic Testing for Inherited Conditions **Explanation of change**: Moved preimplantation testing criteria to Genetic Testing for Inherited Conditions; removed from title of Carrier Screening guidelines.	June 30 2024
Carrier Screening in the Reproductive Setting **(Previously in the Prenatal Setting and Preimplan-**	**Exclusions** The following tests and clinical scenarios are considered not medically necessary: • Carrier screening for conditions known to have adult-onset including, but not limited to, genetic testing for breast cancer (e.g., BRCA gene testing) • Cell-free DNA screening for single gene disorders, microdeletions, or other indications not otherwise specified • Variants with high allele frequencies and low penetrance of a phenotype (e.g., methylene tetrahydrofolate reductase variants) • Whole exome or whole genome assays for the purpose of carrier screening	June 30 2024

tation Genetic Testing	• Molecular screening for conditions where nonmolecular screening techniques can be used (e.g., hereditary hemochromatosis has low penetrance when molecular variants are identified) **Explanation of change:** Clarifications	
Genetic Testing for Inherited Conditions		

Genetic Testing for Inherited Conditions	**Genetic counseling**
	Counseling is strongly recommended prior to genetic testing and should include ALL of the following components:
	• Interpretation of family and medical histories to provide a risk assessment for disease occurrence or recurrence
	• Education about inheritance, genetic testing, disease management, prevention, risk reduction, and resources
	• Counseling to promote informed choices and adaptation to the risk or presence of a genetic condition
	• Counseling for the psychological aspects of genetic testing
	• Counseling should include the following details:
	  ○ Limitations of the testing used
	  ○ A negative result does not indicate heritable risk is zero or low
	  ○ Identification of inconclusive results called variants of uncertain significance is possible
	  ○ Modifications to genetic variants' pathogenicity interpretations can occur and patients may be recontacted with reclassified results in the future
	Note: Post-test counseling should be performed for any diagnostic genetic test result.
	Explanation of change: Clarifications. This is nearly the same Genetic Counseling verbiage used in Hereditary Cancer Testing.
		June 30 2024

Genetic Testing for Inherited Conditions	**Genetic testing for inherited conditions** Genetic testing is considered medically necessary for an individual when ALL the following criteria are met: • The individual is either suspected to have a known genetic condition based on clinical presentation or the individual may be pre-symptomatic but at significant risk based on family history* • The genetic disorder being evaluated has clearly defined gene(s) and pathogenic variants associated with it and the associated test has high sensitivity and specificity to guide clinical decision making • The genetic testing has established analytical and clinical validity and is performed in an appropriately accredited and certified laboratory • Alternate, biochemical, or other clinical tests are not available, provide an indeterminate result or are less effective than genetic testing • The natural history of the disease is associated with significant morbidity and or mortality in affected individuals • Knowledge of the pathogenic variant(s) is expected to directly impact clinical management (predictive, diagnostic, surveillance, therapeutic, or reproductive) of the individual *Family history of the condition(s) being evaluated is present in first-, second- or third-degree relatives as applicable to the inheritance pattern of the condition (i.e., autosomal dominant, autosomal recessive, X-linked). This may also include family history of a known	June 30 2024

	pathogenic variant with or without expression of the condition being evaluated. Confirmatory genetic testing is considered medically necessary for an individual identified to have a pathological variant based on FDA-approved direct-to-consumer genetic testing ONLY if ALL the criteria above have been met. **Testing may be performed only once per lifetime for a given condition.** **Explanation of change:** Clarifications	
Genetic Testing for Inherited Conditions	**Multi-gene panel testing for inherited conditions** Panel testing may be considered when ALL general and condition-specific criteria are met AND ALL of the following criteria are met: • Any multi-gene panel should be as focused as reasonably possible taking into account the prevalence of each gene and the clinical utility of identifying the presence or absence of a pathogenic variant in each gene • Each gene included in the panel must have evidence to show their association with the condition AND pathogenic variants in each gene could affect clinical management • Testing for the more probable genes should be performed before gene panel testing where clinically appropriate **Explanation of change:** Clarifications	June 30 2024
Genetic Testing for Inherited Conditions	**Cardiac conditions** **Post-mortem testing after sudden cardiac death** After sudden cardiac death, genetic testing for pathogenic variants associated with cardiac channelopathies are considered medically necessary when BOTH of the following criteria are met: • The decedent is < 50 years old • The cause of sudden cardiac death remains unexplained despite the clinical history and autopsy, toxicology, and cardiac pathology findings **Explanation of change**: Clarification (only change ALL to BOTH)	June 30 2024
Genetic Testing for Inherited Conditions	**Neurological conditions** Genetic testing for pathogenic variants associated with inherited neurological conditions may be medically necessary when the general requirements OR multi-gene panel criteria listed above are met. Genetic testing for screening or diagnosis of ANY of the following common categories of neurological conditions is considered not medically necessary: • Alzheimer's dementia • Frontotemporal dementias (i.e., Parkinsons's disease, Pick disease, and others) • Motor neuron diseases (such as amyotrophic lateral sclerosis) Note: This guideline does not address testing to guide selection of FDA-approved therapeutics with specific indications based on biomarker test results. Please refer to the Pharmacogenomic Testing guidelines. **Explanation of change:** Clarifications include adding a table summarizing major categories of inherited neurologic conditions.	June 30 2024

Genetic Testing for Inherited Conditions	**Thrombophilia testing** Thrombophilia testing for common pathogenic variants associated with Factor V Leiden or the prothrombin (Factor II) gene G20210A is considered medically necessary to inform anticoagulation decision-making when ANY of the following criteria are met: • Individuals with venous thromboembolism (VTE) at age 50 or under in association with unprovoking/weakly provoking factors, recurrent VTE, or strong family history of VTE • Individuals with VTE involving the cerebral or splanchnic veins • An individual contemplating pregnancy who has a first-degree relative with VTE and a known hereditary thrombophilia • An individual with an unprovoked VTE and low bleeding risk is planning to stop anticoagulation, test for thrombophilia if test results would change this decision • An individual contemplating estrogen use with a first-degree relative with VTE and a known hereditary thrombophilia test for that thrombophilia Not Medically Necessary: MTHFR-gene variant testing for hereditary thrombophilia risk assessment is considered not medically necessary. **Explanation of change**: Clarification only. NMN statement for MTHFR-gene variant testing was in the rationale but should be part of the main body.	June 30 2024

Genetic Testing for Inherited Conditions	**Preimplantation genetic testing**
	Preimplantation genetic testing is considered medically necessary when the embryo(s) is at increased risk of a recognized inherited condition based on ALL of the following:
	• The medical inherited condition and gene variants being evaluated would result in significant morbidity and/or mortality
	• The condition is known to result from a single gene (PGT-M) abnormality, or from structural changes of a gamete provider, preimplantation genetic testing for structural rearrangements (PGT-SR)
	• Gamete providers meet ONE of the following criteria:
	  ○ Both gamete providers are known carriers of the same autosomal recessive condition
	  ○ One partner is a known carrier of an autosomal recessive disorder, and the couple have previously produced offspring affected by that condition
	  ○ At least one gamete provider is a known carrier of an autosomal dominant or sex-linked condition
	  ○ One gamete provider is at greater than or equal to 25% risk to be a carrier of an autosomal dominant single gene condition or an X-linked condition based on family history and is requesting non-disclosure testing (e.g., Huntington's disease; X-linked adrenoleukodystrophy)
	  ○ At least one gamete provider is a carrier of a balanced structural chromosome abnormality
	  ○ At least one gamete provider is an anonymous reproductive donor with unknown/unavailable carrier status when the other gamete provider is a known carrier
	Preimplantation Genetic Testing for aneuploidy (PGT-A) is considered medically necessary when there is a clear heritable indication.
	Heritable indications include:
		June 30 2024

	• X-linked recessive conditions • Sex-limited conditions **Explanation of change**: Expansive for gamete providers in certain scenarios. Clarifications changes. Clarification about PGT-A medical necessity (previous guideline was silent). Moved preimplantation testing criteria from Carrier Screening guidelines.	
Genetic Testing for Inherited Conditions	**Not Medically Necessary:** PGT is considered not medically necessary for ALL the following indications: • PGT-A in the absence of heritable risk • Testing solely to determine if an embryo is a carrier of an autosomal recessive condition • Multifactorial conditions • Polygenic risk scores/disorders (PGT-P) • Variants of unknown significance • Gender selection in the absence of sex-linked or sex-limited risk • Nonmedical traits such as physical characteristics like height and eye color, etc. **Explanation of change:** Clarification on what is not medically necessary. The previous guideline was silent.	June 30 2024

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

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.

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