MASSACHUSETTS

# MEDICAL POLICY ANNOUNCEMENTS

## Posted December 2021

**This document announces new medical policy changes that take effect March 1, 2022.**
Changes affect these specialties:



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

## CARDIOLOGY

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting | 287 | **Policy clarified** to include that placement of implantable cardiac hemodynamic devices in the **inpatient setting is considered investigational.** | December 1, 2021 | Commercial | No action required. |

## CLINICAL LABORATORY

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Identification of Micro-organisms Using Nucleic Acid Probes | 555 | **Policy clarified** to include that urinary tract infection panel is considered investigational. | November 1, 2021 | Commercial Medicare | No action required. |

## DURABLE MEDICAL EQUIPMENT

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Manual and Power Operated Wheelchairs | 365 | Prior authorization requirements for power operated wheelchairs **delayed until further notice**. | Delayed until further notice | Commercial | No action required. |

## GASTROENTEROLOGY

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Percutaneous Electrical Nerve Field Stimulation (PENFS) for Irritable Bowel Syndrome | 922 | **New policy** describing medically necessary indications. | March 1, 2022 | Commercial Medicare | No action required. |

## GENETIC TESTING

The following updates will apply to the AIM 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 AIM via email at aim.guidelines@aimspecialtyhealth.com

| AIM GUIDELINE | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Single Gene and Multifactorial Conditions Genetic Testing Guideline | **Thrombophilia Testing**<br>**Medically necessary criteria for F5/F2 listed** in this section are not changing.<br><br>The following sentence will be deleted:<br>The following test, including but not limited to, is not medically necessary.<br>• MTHFR<br>Chromosomal Microarray Analysis Criteria Deleted from this Guideline in its entirety.<br><br>**Explanation of Change** | March 6, 2022 | Commercial | Prior authorization still required via AIM. |

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| | • Thrombophilia criteria are being incorporated into this guideline. No changes in coverage/stance are suggested. MTHFR is listed in the NMN CPT code table. This sentence is deleted for clarity and to avoid redundancy.<br>• Chromosomal microarray analysis (CMA) criteria and content are being moved from this guideline to the Whole Exome and Whole Genome Sequencing guideline. | | | |
| Hereditary Cancer Susceptibility Genetic Testing Guideline | **Appropriate Use Criteria**<br>At least one of the following:<br>• Individual's personal or family history meets specific testing criteria for at least one of the syndromes listed below<br>• Personal and/or family history is consistent with the hereditary cancer syndrome being tested for when that syndrome is not specifically addressed in these guidelines.<br>**Explanation of Change**<br>Text updates and clarification with no impact on coverage.<br><br>**Germline Testing Following Identification of a Somatic Pathogenic or Likely Pathogenic (P/LP) Variant**<br>**Section Title:** Germline Testing Following Identification of a Somatic Variant<br><br>After a somatic variant is identified in a solid or hematologic malignancy, follow-up germline testing for that variant is medically necessary when the following criteria are met:<br>• There are NCCN Guidelines® category 1 or 2A and/or other published management recommendations specific to germline pathogenic/likely pathogenic (P/LP) variants in the requested gene<br>• There is high clinical suspicion for the variant to be germline based on patient and/or family history OR characteristics of the variant itself (e.g., high allele frequency in tumor sample, well-described | March 6, 2022 | Commercial | Prior authorization still required via AIM. |

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| | founder P/LP variants, concordance between gene and associated tumor type)<br>**Explanation of Change**<br>• Section title revision better encompasses the type of medically necessary somatic variants that prompt high clinical suspicion for the possibility of germline origin. This clarification does not represent a change in coverage stance.<br>• Suggested revisions to criteria streamline similar/redundant text with no impact on coverage stance.<br><br>**National Comprehensive Cancer Network® (NCCN®) Criteria**<br>Genetic testing for the following syndromes is medically necessary when an individual meets the testing criteria outlined in the relevant NCCN® Clinical Practice Guidelines in Oncology:<br>• Hereditary Colorectal Cancer Syndromes<br>○ Hereditary Colorectal Cancer syndromes include: Lynch syndrome, Familial adenomatous polyposis (FAP)/Attenuated familial adenomatous polyposis (AFAP), MYH associated polyposis, Juvenile polyposis syndrome, Peutz-Jeghers syndrome, Serrated Polyposis Syndrome<br>▪ For the purpose of evaluating criteria, Lynch syndrome related cancers include: colorectal, endometrial, keratoacanthoma, stomach, ovarian, small bowel, urothelial, sebaceous adenoma or carcinoma, hepatobiliary, | | | |

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| | pancreas, and brain cancer<br>○ Testing is targeted to the genes listed in NCCN®<br><br>**Genetic/Familial High-Risk Colorectal Cancer, v1.2021**<br>• Hereditary Breast and Ovarian Cancer Syndromes<br>○ Hereditary Breast and Ovarian Cancer syndromes include: Hereditary Breast and Ovarian Cancer syndrome, Cowden syndrome/PTEN Hamartoma tumor syndrome, Li Fraumeni syndrome, and other breast/ovarian cancer susceptibility syndromes<br>▪ For the purpose of evaluating criteria, Hereditary Breast and Ovarian Cancer syndromes related cancers include: breast, ovarian, pancreatic and prostate cancer.<br>○ Testing is targeted to the susceptibility genes (*high and moderate penetrant genes*) listed in NCCN® Genetic/Familial High-Risk Breast, Ovarian and Pancreatic, v1.2022<br>• Multiple Endocrine Neoplasia (type 1 and type 2)<br>○ Testing is targeted to the genes listed in NCCN® Neuroendocrine and Adrenal Tumors, v3.2021<br>○ Diffuse Gastric Cancer<br>○ Testing is targeted to the genes listed in NCCN® Gastric Cancer, v3.2021<br><br>**Explanation of Change:** Suggested revisions clarify/streamline text with no impact on coverage stance. Applicable NCCN Guideline® versions were updated (criteria in new versions do not impact coverage | | | |

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| | stance). The asterisk was also removed from the title of this section for clarification (an additional asterisk is found in the NCCN® section of the Professional Society Guidelines which better directs the reader to the asterisked text).<br><br>**Hereditary Paraganglioma-Pheochromocytoma Syndrome**<br>Section Title: Hereditary Paraganglioma-Pheochromocytoma Syndromes Single gene testing or a targeted gene panel is medically necessary for hereditary paraganglioma-pheochromocytoma (PGL/PCC) syndromes when all of the following criteria are met:<br>• Individual meets general criteria for hereditary cancer genetic testing (above)<br>• Individual* with pheochromocytoma or paraganglioma<br>• Other syndromes and causes of PGL/PCC have been ruled out (e.g.,multiple endocrine neoplasia)<br><br>*Testing can be extended to first- or second- degree relatives if the affected proband is unavailable for testing. Single-site testing is medically necessary for those at risk for a known familial P/LP variant.<br><br>**Explanation of Change**<br>Suggested revisions are clarification/streamlining redundancy with no impact on coverage criteria. | | | |
| Reproductive Carrier Screening and Prenatal Diagnosis Genetic Testing Guideline | **Carrier Screening**<br>Familial Disease<br>Fragile X<br>Cystic Fibrosis<br>Spinal Muscular Atrophy<br>Hemoglobinopathies<br>Ashkenazi Jewish Carrier Screening<br>Other Ethnicities<br>**Carrier Screening Not Clinically Appropriate**<br>**Explanation of Change**<br>Suggested revisions are clarification/streamlining with no impact on coverage criteria. | March 6, 2022 | Commercial | Prior authorization still required via AIM. |

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| | **Appropriate Use Criteria (Hemoglobinopathies section**<br>Hemoglobinopathy genetic carrier screening is medically necessary when any of the following criteria are met:<br>• Clinical or laboratory features (e.g., CBC, hemoglobin electrophoresis) are suggestive of a hemoglobinopathy<br>• Results of testing by conventional studies (e.g., electrophoresis, liquid chromatography, isoelectric focusing) yield equivocal results and a definitive diagnosis remains uncertain<br>• A definitive diagnosis is known but specific P/LP variant identification is necessary for reproductive options/interventions, e.g., preimplantation genetic testing or prenatal diagnosis<br>**Explanation of Change**<br>Suggested revisions are clarification/streamlining redundancy with no impact on coverage criteria.<br><br>**Appropriate Use Criteria (Other Ethnicities and Carrier Screening Not Clinically Appropriate sections)**<br>**Other Ethnicities**<br>Carrier screening for additional conditions may be considered medically necessary if the patient is at increased risk to be a carrier based on their ethnicity, including but not limited to:<br>• Tay-Sachs carrier screening for individuals with French Canadian ancestry<br>• Maple syrup urine disease (MSUD) screening for individuals with Mennonite ancestry Multi-gene panel testing is medically necessary when the individual's personal and/or family history meets one or more criteria above for all of the genes on the panel.<br><br>**Carrier Screening Not Clinically Appropriate** | | | |

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| | The following tests are not medically necessary for carrier screening in the general population:<br>• Thrombophilia screening<br>• Whole exome sequencing<br><br>**Explanation of Change**<br>Multi-gene panel testing (historically referred to as expanded carrier screening panels) will now be addressed in the "Other Ethnicities" section. This suggested revision does not reflect a change in coverage stance. We are currently evaluating the ACMG Practice Resource (Gregg et al. 2021) that calls for universal pan-ethnic carrier screening using a panel of 113 genes. At this time, we feel the data rising to the rigor of our evidentiary standards is lacking. We look forward to further conversations with our clients, other professional society responses, and additional evidence to substantiate ACMG recommendations. Other programmatic ways to address 81443 should also be part of ongoing discussions.<br><br>**Preimplantation Genetic Testing of Embryos and Preimplantation Genetic Testing for Aneuploidy**<br>**Preimplantation Genetic Testing of Embryos**<br>Preimplantation genetic testing is not medically necessary for any other indication, including but not limited to the following:<br>• human leukocyte antigen (HLA) typing of an embryo to identify a future suitable stem-cell tissue or organ transplantation donor<br>• testing solely to determine if an embryo is a carrier of an autosomal recessively-inherited disorder<br>• testing for a multifactorial condition testing for variants of unknown significance<br>• nonmedical gender selection<br>• nonmedical traits<br>• Preimplantation genetic testing for aneuploidy (PGT-A) by any testing methodology for any indication | | | |

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| | DELETE<br>Preimplantation Genetic Testing for Aneuploidy section<br>**Explanation of Change**<br>Suggested revisions are clarifications/streamlining of text with no impact on coverage stance.<br><br>**<u>Prenatal Cell-Free DNA Screening</u>**<br>Prenatal cell-free DNA screening is not medically necessary for the following indications:<br>• high-order multiple gestations (i.e., triplets or higher)<br>• multiple gestation pregnancies with fetal demise, vanishing twin, one or more anomalies detected in one fetus<br>• miscarriage (including recurrent pregnancy loss) or fetal demise<br><br>SensiGene® (81479 or 81403) testing is medically necessary in a single gestation pregnancy when all of the following criteria are met:<br>• a maternal anti-D antibody has been identified<br>• the paternal Rh genotype is determined to be heterozygous or is unknown<br>• the results will impact antenatal care<br><br>**Explanation of Change**<br>• Criteria update: the criteria for SensiGene® testing was deleted in the prior guideline iteration (effective September 6, 2021) because the test was no longer commercially available. The test has returned, so original criteria (with the same coverage stance) are being added back to this guideline.<br>• Other suggested revisions are clarifications with no impact on coverage stance.<br><br>**<u>Prenatal Molecular Genetic Testing of a Fetus and Reproductive Genetic Testing for Recurrent Pregnancy Loss</u>** | | | |

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| | **Prenatal Molecular Genetic Testing of a Fetus**<br>*Note: The criteria below do not apply to cytogenetic testing (e.g., karyotype, chromosome analysis).*<br><br>Single gene, multi-gene, or chromosomal microarray prenatal genetic testing is medically necessary when the results of the genetic test will impact clinical decision-making and the requested method is scientifically valid for the suspected condition.<br><br>Prenatal molecular genetic testing in a fetus for familial variants of unknown significance is not medically necessary.<br><br>**Reproductive Genetic Testing for Pregnancy Loss**<br>*Note: The criteria below do not apply to cytogenetic testing (e.g., karyotype, chromosome analysis).*<br><br>Chromosome microarray (CMA) testing on products of conception is medically necessary for:<br>• evaluation of recurrent pregnancy loss*<br>• evaluation of intrauterine fetal demise (IUFD) or stillbirth after 20 weeks of gestational age<br>• evaluation of a pregnancy loss with one or more major structural anomalies<br>**Recurrent pregnancy loss is defined by two or more unexplained pregnancy losses.*<br><br>Genetic testing (using single gene or multi-gene panel assays) for genes associated with thrombophilia, e.g., F2, F5, MTHFR, is not medically necessary.<br><br>**Explanation of Change**<br>Suggested revisions are clarifications, streamlining and re-organizing of text with no impact on coverage stance. | | | |
| Somatic and Hematologic | **Cell-free testing (e.g., cfDNA, ctDNA, liquid biopsy)** in the following scenarios is medically | March 6, 2022 | Commercial | Prior authorization |

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| Tumors Genetic Testing Guideline | necessary when General Coverage Criteria or FDA Companion Diagnostic Coverage Criteria above are met:<br>• Metastatic Castrate-Resistant Prostate Cancer (mCRPC)<br>  ○ FoundationOne® Liquid CDx is medically necessary in men with metastatic castrate resistant prostate cancer (mCRPC) when the patient meets criteria per the FDA label for treatments for which this test has been approved as a companion diagnostic<br>• Ovarian, Fallopian Tube, or Primary Peritoneal Cancer<br>  ○ FoundationOne® Liquid CDx is medically necessary if tumor is unavailable in women with ovarian, fallopian tube, or primary peritoneal cancer when the patient meets criteria per the FDA label for treatment(s) for which this test has been approved as a companion diagnostic<br>• Advanced or Metastatic Breast Cancer<br>  ○ therascreen® PIK3CA testing is medically necessary using liquid biopsy if tumor is unavailable for advanced or metastatic breast cancer when the patient meets criteria per the FDA label for treatments for which this test has been approved as a companion diagnostic<br>• Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)<br>  ○ Initial Biomarker Determination<br>  ▪ FDA approved companion diagnostic tests | | | still required via AIM. |

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| | (i.e., cobas EGFR Mutation Test v2, FoundationOne® Liquid CDx, or Guardant360® CDx) or a targeted multi-gene panel, e.g., ctDxLung™, are medically necessary when tissue-based testing cannot be performed, e.g., insufficient tissue<br>○ At time of progression on an EGFR tyrosine kinase inhibitor (TKI) therapy<br>▪ Targeted cell-free testing (i.e., cobas EGFR Mutation Test v2) is medically necessary<br>• Targeted cell-free testing is not medically necessary when progression is on Osimertinib Cell-free testing is not medically necessary when the patient already meets criteria for treatment without the need for additional testing (e.g., patient meets criteria based on known genetic results or biomarker status is not required).<br><br>**Explanation of Change**<br>• Revisions to the first sentence reference new formatting for headings in the guideline and do not reflect any changes to the current coverage stance.<br>• Revisions to mCRPC; ovarian, fallopian tube or peritoneal cancer; and advanced or metastatic breast cancer are clarifications to streamline text that do not impact current coverage stance.<br>• The FDA issued a CDx approval in July 2021 for MET exon 14 skipping mutations to treat with capmatinib. FoundationOne® Liquid | | | |

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| | • CDx now has FDA CDx approval for EGFR, ALK fusions, and MET exon skipping mutations. Other revisions to this criteria reflect clarifications and no changes in coverage stance.<br><br>**Minimal Residual Disease (MRD) Testing**<br>Targeted testing with prospective evidence of clinical utility for the tumor type and disease characteristics is medically necessary.<br>**Explanation of Change**<br>Clarification of text with no impact on current coverage stance.<br>**Targeted Molecular Testing for NTRK Fusions**<br>Targeted molecular testing for NTRK1/2/3 fusions is medically necessary when general coverage criteria above are met for any of the following indications:<br>**Explanation of Change**<br>Clarification of text with no impact on current coverage stance.<br><br>**Cancer Screening (historically referred to as Prostate Cancer (symptomatic cancer screening) section)**<br>Formatting changes (addition of heading/subheading), include:<br>**Cancer Screening** *(new heading)*<br>**Population Based Cancer Screening** *(new subheading, see criteria below)*<br>**Prostate Cancer (symptomatic cancer screening)** *(current subheading)*<br><br>Text/criteria changes, include:<br>**Population Based Cancer Screening**<br>Multi-Cancer Early Detection (MCED) testing is not medically necessary.<br>**Prostate Cancer (symptomatic cancer screening)** *(current subheading)*<br><br>Text/criteria changes, include:<br>**Population Based Cancer Screening**<br>Multi-Cancer Early Detection (MCED) testing is not medically necessary. | | | |

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| | **Prostate Cancer (symptomatic cancer screening)** *(current subheading)*<br>(*additional text not listed here*)<br>Assays not listed above are considered not medically necessary. Serial testing and/or concurrent testing with multiple assays is not medically necessary.<br><br>**Explanation of Change**<br>• Formatting changes to add a general heading, Cancer Screening, and an additional subheading, Population Based Cancer Screening, are proposed to allow addressing other forms of cancer screening. These revisions do not reflect changes to coverage stance- simply clarifications.<br>• Population Based Cancer Screening: As a clinical space, multi-cancer early detection tests are receiving increasing levels of attention. Published data is insufficient to support population-based screening. It was pertinent to add a NMN statement. This is a clarification, not a change in coverage stance.<br>• Prostate Cancer (symptomatic cancer screening): the suggested revision is clarification of our stance to support denials preventing abuse of testing beyond validated scenarios | | | |
| Pharmacogenomic and Thrombophilia Genetic Testing Guideline | **Scope**<br>**Guideline Title:** Pharmacogenomic Testing<br>**Scope:** Pharmacogenomic testing broadly describes how one's genome, or multiple genes, can influence drug response while more targeted pharmacogenetic testing describes genotyping a specific gene to predict response to certain medications. This document addresses pharmacogenomic testing for the purpose of informing medication selection, dosage, and risk of adverse side effects. This guideline does not address tumor testing (see Molecular Testing of Solid and Hematologic Tumors and Malignancies) or | March 6, 2022 | Commercial | Prior authorization still required via AIM. |

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| | germline testing (see Genetic Testing for Hereditary Cancer Susceptibility) performed to direct treatment decisions or genetic testing to generate polygenic risk scores (see Genetic Testing for Single-Gene and Multifactorial Conditions). All tests listed in these guidelines may not require prior authorization; please refer to the health plan.<br><br>**Explanation of Change**<br>Suggested revisions are formatting changes or clarifications and do not impact current coverage stance.<br><br>**Appropriate Use Criteria (Thrombophilia Testing)**<br>**Thrombophilia Testing:** criteria deleted and moved to Genetic Testing for Single-Gene and Multifactorial Conditions.<br>**Explanation of Change**<br>Thrombophilia criteria and content are being moved to the Genetic Testing for Single-Gene and Multifactorial Conditions guideline for clarity. The field of Pharmacogenomics is separate and distinct from genetic testing for thrombophilia and as ordering patterns and the testing landscape have changed, the criteria for thrombophilia testing should be housed in the guideline that encompasses general testing for genetic disease and not pharmacogenomics. | | | |
| **Chromosomal Microarray Analysis, Whole Exome and Whole Genome Sequencing Guideline** | **Scope**<br>This document addresses the diagnostic use of chromosomal microarray analysis (CMA) and whole exome sequencing (WES) in the evaluation of rare disease. It does not address the use of WES as a technology for tumor profiling (see Molecular Testing of Solid and Hematologic Tumors and Malignancies). This document also addresses whole genome sequencing (WGS) as well as other broad scale profiling, e.g. whole transcriptome analysis and genome mapping. All tests listed in these guidelines may not require prior authorization or may | March 6, 2022 | Commercial | Prior authorization still required via AIM. |

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| | have separate coverage criteria; please refer to the health plan.<br><br>**<u>Genetic Counseling Requirement</u>**<br>**Genetic testing, i.e., whole exome sequencing, included in these Guidelines is covered when:**<br>**Explanation of Change**<br>The genetic counseling requirement does not apply to genetic testing using chromosomal microarray analysis, now included in this guideline. Whole exome sequencing is the medically necessary genetic testing for which this requirement is applicable. This was clarified with the revision.<br>**<u>Whole Exome Sequencing (Phenotype Suspicious of a Genetic Disorder, Epilepsy and Hearing Loss sections)</u>**<br><br>**Whole Exome Sequencing**<br>Whole exome sequencing (WES) (81415 with or without 81416) is medically necessary for any of the following clinical scenarios when all of the general criteria for WES testing (below) are also met.<br><br>**Phenotype Suspicious for a Genetic Diagnosis**<br>Testing is ordered after an individual has been evaluated by a board-certified medical geneticist or other board-certified specialist physician with specific expertise in the conditions being tested for and relevant genes, AND any of the following:<br>• Individual with multiple major structural or functional congenital anomalies affecting unrelated organ systems (including major metabolic disorders), **OR**<br>• Individual with one major structural or functional congenital anomaly and two or more minor structural anomalies, **OR**<br>• Individual with one major structural congenital anomaly and a family history strongly implicating a genetic etiology **OR**<br>• Individual with known or suspected developmental and epileptic encephalopathy (onset | | | |

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| | before three years of age) for which likely non-genetic causes of epilepsy (e.g., environmental exposures; brain injury secondary to complications of extreme prematurity, infection, trauma) have been excluded, **OR**<br>• Individual diagnosed with global developmental delay* following formal assessment by a developmental pediatrician or neurologist, **OR**<br>• Individual diagnosed with a moderate/severe/profound intellectual disability** following formal assessment by a developmental pediatrician or neurologist, **OR**<br>• Individual with confirmed bilateral sensorineural hearing loss of unknown etiology<br>*Global developmental delay is defined as significant delay in younger children, <5 years of age, in at least two of the major developmental domains: gross or fine motor; speech and language; cognition; social and personal development; and activities of daily living.<br><br>**Moderate/severe/profound intellectual disability as defined by DSM-5 diagnosed by 18 years of age.<br><br>**Explanation of Change**<br>• There is now sufficient evidence that the diagnostic yield and clinical utility has been proven for WES as a first-tier test in individuals with global developmental delay (gDD) or intellectual disability (ID) (as defined above). The revised WES criteria streamlines current criteria with an expansion for testing applicable only to those with ID/gDD.<br><br>**<u>Whole Exome Sequencing (General Criteria for WES Testing)</u>**<br>WES is not medically necessary in the following scenarios:<br>• Testing using cell-free DNA<br>• Preimplantation testing of an embryo | | | |

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| | • Genetic carrier screening<br>• Asymptomatic screening<br>• Oncology indications<br>• Isolated mild intellectual disability<br>• Isolated autism spectrum disorder<br>**Explanation of Change**<br>• The addition of "asymptomatic screening" is a clarification- no change in stance. "Executive health screens" outside the realm of reproductive testing are gaining popularity, thus a criterion addressing this testing was added.<br>• The addition of "isolated mild intellectual disability and autism spectrum disorder" are clarifications and do not represent a change in coverage stance.<br><br>**<u>Chromosomal Microarray Analysis</u>**<br>*Current coverage criteria for CMA from the Genetic Testing for Single-Gene and Multifactorial Conditions guideline were inserted with the following changes:*<br>Chromosomal microarray analysis (CMA) is medically necessary for any of the following indications:<br>• Non-syndromic autism spectrum disorder<br>• Non-syndromic global developmental delay or intellectual disability*<br>• Individual with multiple major structural or functional congenital anomalies affecting unrelated organ systems (including major metabolic disorders)*<br>• Known or suspected developmental and epileptic encephalopathy (onset before three years of age) for which likely non-genetic causes of epilepsy (e.g., environmental exposures; brain injury secondary to complications of extreme prematurity, infection, trauma) have been excluded*<br>*CMA is intended for use in the detection of chromosomal duplications and deletions only and is therefore indicated when the possibility of microdeletion or microduplication syndromes/conditions are suspected. | | | |

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| | It cannot detect other common variant types (e.g., sequence variants). If sequence variants are high on the differential diagnosis, please see whole exome sequencing criteria above.<br><br>**Explanation of Change**<br>The asterisk was added to the non-syndromic global developmental delay or intellectual disability criterion to reflect the gDD/ID criterion added to WES criteria (the asterisk also now directs one to the whole exome sequencing criteria "below" since CMA is now part of the same guideline).<br>**Whole Genome Sequencing**<br>Whole genome sequencing (WGS) is not medically necessary*.<br>Whole genome sequencing of the transcriptome (RNA sequencing) and genome mapping are not medically necessary.<br>**Explanation of Change**<br>The addition of "genome mapping" is a clarification and does not represent a change in coverage stance. | | | |

## MULTISPECIALTY - PRIOR AUTHORIZATION INFORMATION

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Medicare Advantage Management | 132 | **Policy clarified.** Outpatient prior authorization requirements for **Medicare Advantage PPO** effective date is January 1, 2022. | January 1, 2022 | Medicare | Prior authorization required for certain procedures for Medicare Advantage PPO products. |
| Outpatient Prior Authorization Code List for Commercial | 072 | Outpatient prior authorization requirements for Commercial PPO and EPO is **delayed until further notice**. | Delayed until further notice | Commercial | No action required. |

## NEUROLOGY NEUROSURGERY AND ORTHOPEDICS

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Epidural Steroid Injections for Neck and Back Pain | 690 | **Enforcement update.** Diagnoses codes list added. New diagnoses-to-CPT codes edit implemented. Policy criteria unchanged. | January 7, 2022 | Commercial | No action required. |
| Evaluation of Biomarkers for Alzheimer Disease (AD) | 581 | **Policy clarified.** Additional evidence review added for use of cerebrospinal fluid biomarkers in the management of mild cognitive impairment or mild dementia due to who are being evaluated for the initiation or continuation of amyloid beta targeting therapy. These indications are considered investigational. | December 1, 2022 | Commercial Medicare | No action required. |
| Medical Technology Assessment Noncovered Services | 400 | **Ongoing investigational statement transferred to MP #482** Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation. | December 1, 2022 | Commercial | No action required. |
| Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplasty and Intraosseous Basivertebral Nerve Ablation | 482 | **Policy clarified.** Policy statements updated to include ongoing investigational statement on intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept® system) for the treatment of vertebrogenic back pain. | December 1, 2022 | Commercial | No action required. |

## PHARMACY

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Medicare Advantage Part B Step Therapy | 020 | Mvasi and Zirabev removed as Step 1 requirement prior to use of Beovu, Eylea, Lucentis, Macugen based on updated CMS guidance. | December 1, 2021 | Medicare | Providers will be required to use Avastin prior to use of Beovu, Eylea, Lucentis, Macugen based on updated CMS guidance. |

## PLASTIC SURGERY

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Reduction Mammaplasty for Breast-Related Symptoms | 703 | **Policy clarified.** New medically necessary indications described for repeat reduction mammoplasty. | December 1, 2021 | Commercial | Outpatient prior authorization still required. |
| Gender Affirming Services (Transgender Services) | 189 | **Policy clarified.** Policy statement on surgical procedures revised to clarify that surgical procedures may be done in stages as needed.<br><br>Policy statement on facial feminization or masculinization clarified to include scalp advancement (only as needed in conjunction with forehead contouring).<br><br>Policy statement revised to clarify that hormone therapy is not required for transmasculine or gender diverse members requesting surgical chest procedures. | December 1, 2021 | Commercial Medicare | Outpatient prior authorization still required for surgical procedures. |

## PSYCHIATRY

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
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| Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders | 297 | **Policy clarified** to specify using an FDA-cleared device and modality. Policy statements unchanged. | December 1, 2021 | Commercial | Outpatient prior authorization still required. |

## UROLOGY

| POLICY TITLE | POLICY NO. | POLICY CHANGE SUMMARY | EFFECTIVE DATE | PRODUCTS AFFECTED | PROVIDER ACTIONS REQUIRED |
|---|---|---|---|---|---|
| Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence | 471 | **Policy revised.** Medically necessary policy statement in men and women with stress urinary incontinence who have failed appropriate conservative therapy expanded to include polyacrylamide hydrogel, which is now FDA approved. | March 1, 2022 | Commercial | No action required. |

## New 2020 Category III CPT Codes

**All** category III CPT Codes, including new 2020 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.com/common/en_US/medical_policies/medcat.htm 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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