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Medical Policy Carelon Genetic Testing Management Program

Policy Number: 954

BCBSA Reference Number: N/A NCD/LCD: N/A Effective Date: January 1, 2019

Related Policies

- Carelon Genetic Testing Management Program CPT and HCPCS Codes, #957
- Biomarkers for the Diagnosis and Cancer Risk Assessment of Prostate Cancer, #336
- Cardiovascular Risk Panels, #664
- Preimplantation Genetic Testing, #088
- Medicare Advantage Management, #132

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Overview:

Commercial Products

Effective January 1, 2019, BCBSMA has delegated utilization management of molecular genetic testing to Carelon Medical Benefits Management for **Commercial products** only.

The Genetic Testing Management Program **requires prior authorization** for molecular genetic tests per the medical necessity criteria reflected in the Carelon Medical Benefits Management Clinical Guidelines for Commercial products effective January 1, 2019.

Medicare Advantage Products

Effective January 1, 2025, BCBSMA has delegated utilization management of molecular genetic testing to Carelon Medical Benefits Management for Medicare Advantage products.

The Genetic Testing Management Program **requires prior authorization** for molecular genetic tests per the medical necessity criteria reflected in the Carelon Medical Benefits Management Clinical Guidelines for Medicare Advantage products effective January 1, 2025.

The Carelon Medical Benefits Management Clinical Guidelines are based on peer-reviewed literature and recommendations from evidence-based research centers such as (but not limited to): The American College of

Medical Genetics (ACMG), The American College of Obstetrics and Gynecologists (ACOG), the American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN).

Policy and Coverage Criteria for Commercial and Medicare Advantage Products:

The Carelon Medical Benefits Management Clinical Guidelines include medical necessity criteria for genetic tests in the following categories:

<u>Genetic Testing for Hereditary Cancer Susceptibility</u> https://guidelines.carelonmedicalbenefitsmanagement.com/

Genetic Testing for Hereditary Cardiac Disease https://guidelines.carelonmedicalbenefitsmanagement.com/

Genetic Testing for Pharmacogenetic and Thrombophilia https://guidelines.carelonmedicalbenefitsmanagement.com/

<u>Genetic Testing for Reproductive Carrier Screening and Prenatal Diagnosis</u> <u>https://guidelines.carelonmedicalbenefitsmanagement.com/</u>

<u>Genetic Testing for Single-Gene and Multifactorial Conditions</u> <u>https://guidelines.carelonmedicalbenefitsmanagement.com/</u>

Genetic Testing for Whole Exome and Genome Sequencing https://guidelines.carelonmedicalbenefitsmanagement.com/

Molecular Testing of Solid and Hematologic Tumors and Malignancies https://guidelines.carelonmedicalbenefitsmanagement.com/

The following BCBSMA medical policy is used instead of the Carelon guideline on reproductive carrier screening and prenatal diagnosis:

- <u>BCBSMA Medical Policy #088 Preimplantation Genetic Testing (including preimplantation genetic diagnosis)</u>. The policy is only available on the BCBSMA medical policy website.
- Prior authorization is required through BCBSMA. <u>See instructions below</u>.

The utilization management of molecular genetic testing through Carelon Medical Benefits Management does **not** include the following:

- Cytogenetics
- Human Leukocyte Antigen (HLA) testing
- Human Platelet Antigen (HPA) testing.

For a list of specific tests, CPT codes, and HCPCS codes that require prior authorization, see Carelon Genetic Testing Management Program CPT and HCPCS Codes, #<u>957</u>.

CPT codes and HCPCS that apply to BCBSMA Medical Policy #<u>088</u> are found on the policy. Do not use BCBSMA Policy #<u>957</u> to look up codes for Preimplantation Genetic Testing.

Molecular genetic/genomic testing that does not meet coverage criteria listed in these clinical guidelines may be considered experimental/investigational or not medically necessary, and therefore not covered.

Genetic testing is covered only when the patient meets coverage criteria outlined in the corresponding guideline or in the BCBSMA Medical Policy. Carelon guidelines are available at <u>Guidelines.carelonmedicalbenefitsmanagement.com.</u>

Requesting Prior Authorization Information through Carelon Medical Benefits Management:

To request prior authorization for the following products, please see instructions below.

- Commercial Managed Care (HMO and POS) and Commercial PPO/EPO (PA requirement in effect since 1/1/2019)
- Medicare HMO Blue and Medicare PPO Blue (PA requirement effective 1/1/2025)
- 1. Through the Blue Cross Blue Shield of Massachusetts website:
 - Log in to your Blue Cross Blue Shield of Massachusetts Provider Central account at <u>www.bluecrossma.com/provider</u>.
 - Click eTools> and then to Carelon Medical Benefits Management
 - Click Go Now
- 2. Going directly to Carelon ProviderPortal (registration is required)
 - Go to <u>www.providerportal.com</u>
 - Or calling 1-866-745-1783 (when applicable).

Requesting Prior Authorization Information through BCBSMA:

This only applies to Medical Policy #088 Preimplantation Genetic Testing.

To request prior authorization for the following products: Commercial Managed Care (HMO and POS) and Commercial PPO and Indemnity and Medicare HMO Blue and Medicare PPO Blue, please see instructions below.

Through the Blue Cross Blue Shield of Massachusetts website:

- Log in to your Blue Cross Blue Shield of Massachusetts Provider Central account at <u>www.bluecrossma.com/provider</u>.
- Prior authorization is required for the following biopsy codes only:
 - 89290 Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
 - 89291 Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos
- No additional authorization is required for genetic testing when the biopsy has been approved.

List of Retired BCBSMA Genetic Testing Medical Policies:

The following BCBSMA Genetic Testing Medical Policies will be retired effective January 1, 2019. For the list of impacted CPT and HCPCS codes, see Carelon Genetic Testing Management Program CPT and HCPCS Codes, <u>#957</u>. **Note:** These policies will no longer be available on the BCBSMA website as of this date. For medically necessary indications, see the <u>Carelon Medical Benefits Management Clinical Guidelines for non-oncologic and oncologic conditions</u>.

Medical Policy Title	Policy Number
Cardiology	
Gene Expression Testing in the Evaluation of Patients with Stable Ischemic Heart Disease	349
Genetic Testing for Congenital Long QT Syndrome	082
Genetic Testing for Dilated Cardiomyopathy	601
Genetic Testing for Marfan Syndrome, Thoracic Aortic Aneurysms and Dissections, and Related Disorders	729
Genetic Testing for Predisposition to Inherited Hypertrophic Cardiomyopathy	909
Genotyping for 9p21 Genetic Polymorphisms to Predict Cardiovascular Disease Risk	340
General Genetics	
DNA-Based Testing for Adolescent Idiopathic Scoliosis	545
General Approach to Evaluating the Utility of Genetic Panels	734
General Approach to Genetic Testing	735
Genetic Testing for Alpha Thalassemia	520
Genetic Testing for Alpha-1 Antitrypsin Deficiency	906
Genetic Testing for CHARGE Syndrome	540
Genetic Testing for Facioscapulohumeral Muscular Dystrophy	535
Genetic Testing for Familial Alzheimer's Disease	580
Genetic Testing for Helicobacter Pylori Treatment	288

Genetic Testing for Hereditary Hemochromatosis	908		
Genetic Testing for Hereditary Pancreatitis	516		
Genetic Testing for Heterozygous Familial Hypercholesterolemia	796		
Genetic Testing for Interiozygous raminal hypercholesterolemia	802		
Genetic Testing for Lactase Insufficiency	565		
Genetic Testing for Macular Degeneration			
Genetic Testing for Muscular Dystrophies			
Genetic Testing of CADASIL Syndrome			
Human Leukocyte Antigen Testing for Celiac Disease	357 567		
Miscellaneous Genetic and Molecular Diagnostic Tests	712		
Whole Exome Sequencing	457		
Hereditary Cancer			
Genetic Cancer Susceptibility Panels Using Next Generation Sequencing	574		
Genetic Testing for Cutaneous Malignant Melanoma	300		
Genetic Testing for Fanconi Anemia	714		
Genetic Testing for Hereditary Breast and Ovarian Cancer	245		
Genetic Testing for Inherited Susceptibility to Colon Cancer, Including Microsatellite	226		
Instability Testing	220		
Genetic Testing for Li-Fraumeni Syndrome	684		
Genetic Testing for PTEN Hamartoma Tumor Syndrome	615		
Use of Common Genetic Variants (Single Nucleotide Variants) to Predict Risk of	252		
Nonfamilial Breast Cancer			
Musculoskeletal			
Genetic Testing for Limb-Girdle Muscular Dystrophies	738		
Genetic Testing for Mitochondrial Disorders	685		
Neurology/Psychiatry			
Genetic Testing for Developmental Delay/Intellectual Disability, Autism Spectrum Disorder	228		
and Congenital Anomalies			
Genetic Testing for Epilepsy	668		
Genetic Testing for FMR1 mutations (including Fragile X Syndrome)	907		
Genetic Testing for Mental Health Conditions	669		
Genetic Testing for Neurofibromatosis	793		
Genetic Testing for Nonsyndromic Hearing Loss	452		
Genetic Testing for Rett Syndrome	803		
Genetic Testing for the Diagnosis of Inherited Peripheral Neuropathies	569		
Oncology			
Analysis of MGMT Promoter Methylation in Malignant Gliomas	587		
Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in	055		
Patients with Breast Cancer			
BCR-ABL1 Testing in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia	612		
Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid	797		
Biopsy) – Retired effective 1.4.2021			
BRAF Gene Mutation Testing to Select Melanoma Patients for BRAF Inhibitor Targeted	398		
Therapy			
Detection of Circulating Tumor Cells in the Management of Patients with Cancer	265		
Expanded Molecular Panel Testing of Cancers to Identify Targeted	790		
Therapies			
Gene Expression Based Assays for Cancers of Unknown Primary	614		
Gene Expression Profiling for Cutaneous Melanoma	056		
Gene Expression Profiling for Uveal Melanoma	683		
Genetic and Protein Biomarkers for the Diagnosis and Cancer Risk Assessment of	333		
Prostate Cancer: TMPRSS Fusion Genes in Prostate Cancer (using PCR); Mitochondrial			
DNA Mutation Testing (eg, Prostate Core Mitomics Test™); Candidate Gene Panels; Gene			
Hypermethylation Testing (eg, ConfirmMDx®)			
Genetic Testing for CHEK2 Mutations for Breast Cancer	741		
Genetic Testing for FLT3 and NPM1 Mutations in Acute Myeloid Leukemia	693		

Genetic Testing for Germline Mutations of the RET Proto-Oncogene in Medullary	564		
Carcinoma of the Thyroid			
KIT (c-KIT) Mutation Analysis			
KRAS and BRAF Mutation Analysis in Metastatic Colorectal Cancer			
Microarray-based Gene Expression Analysis for Prostate Cancer Management			
Microarray-Based Gene Expression Profile Testing for Multiple Myeloma Risk Stratification	477		
Moderate Penetrance Variants Associated with Breast Cancer in Individuals at High Breast	722		
Cancer Risk			
Molecular Analysis for Targeted Therapy of Non-Small-Cell Lung Cancer	563		
Molecular Markers in Fine Needle Aspirates of the Thyroid	913		
Molecular Testing for the Management of Pancreatic Cysts or Barrett Esophagus	566		
Multigene Expression Assay for Predicting Recurrence in Colon Cancer	239		
Non-BRCA Breast Cancer Risk Assessment - e.g., OncoVue	188		
Proteogenomic Testing for Patients with Cancer (GPS Cancer Test)	838		
Pharmacogenetics			
Cytochrome p450 Genotyping	256		
Genetic Testing for Lipoprotein(a) Variant(s) as a Decision Aid for Aspirin Treatment	339		
Genetic Testing for Statin-Induced Myopathy	575		
Genetic Testing for Tamoxifen Treatment	067		
Genetic Testing for Warfarin Dose	214		
KIF6 Genotyping for Predicting Cardiovascular Risk and or Effectiveness of Statin Therapy	129		
Laboratory and Genetic for Use of 5-Fluorouracil in Patients with Cancer	318		
Pharmacogenetic Testing for Pain Management	724		
Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines	096		
Reproductive			
Carrier Screening for Genetic Diseases	666		
Chromosomal Microarray Testing for the Evaluation of Pregnancy Loss	686		
Invasive Prenatal (Fetal) Diagnostic Testing	708		
Noninvasive Fetal RHD Genotyping Using Cell-Free Fetal DNA	667		
Noninvasive Prenatal Screening for Fetal Aneuploidies and Microdeletions Using Cell-Free Fetal DNA	628		

Policy History

Date	Action
1/2025	Policy revised. Carelon Genetic Testing Management Program document MP #954 updated to include that prior authorization is required for Medicare Advantage through Carelon. Effective 1/2025.
	Note: Prior to 1/2025, prior authorization through Carelon was not required for Medicare Advantage products. Medicare NCDs and LCDs through the CMS website for genetic testing guidelines were followed for Medicare Advantage.
3/2023	AIM Specialty Health changed its name to Carelon Medical Benefits Management.
10/2022	Policy #790 Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies is retired. AIM Guidelines for Molecular Testing of Solid and Hematologic Tumors and Malignancies will be used to determine coverage. Effective 9/4/2022. For medical necessity criteria, see Carelon Medical Benefits Management Clinical Guidelines.
1/2021	Policy #797 Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy) is retired. For medical necessity criteria, see Carelon Medical Benefits Management Clinical Guidelines. Effective 1/4/2021.
1/2019	Policy issued 1/1/2019.

Disclaimer

Coverage is subject to applicable benefit contract. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

Member's medical records must document that services are medically necessary for the care provided. BCBS MA maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available upon request. Failure to produce the requested information may result in denial or retraction of payment.

References

Carelon Medical Benefits Management Clinical Guidelines