Medical Policy

DNA Testing of Stool Samples with Cologuard™ to Screen for Colorectal Cancer

Policy Number: OCA 3.63
Version Number: 1
Version Effective Date: 07/08/17

Product Applicability

All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers fecal DNA testing to screen for colorectal cancer to be medically necessary for a member (regardless of gender) when the Plan’s medical criteria are met. Prior authorization is required. Review the Plan’s medical policy, Genetic Testing for Hereditary Colorectal Cancer (policy number OCA 3.64), rather than this policy for genetic mutation testing for hereditary colorectal cancer.

It will be determined during the Plan’s prior authorization process if the testing is considered medically necessary for the requested indication. See the Plan’s policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. Refer to the Plan’s policy,
**Experimental and Investigational Treatment** (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

**Plan prior authorization is required for all molecular and chromosomal genetic testing**, except for prenatal genetic screening tests for a member with one of the pregnancy diagnosis codes specified in the Applicable Coding section of the Genetic Testing Guidelines and Pharmacogenetics medical policy (policy number OCA 3.7272), Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies medical policy (policy number OCA 3.573), or Genetic Testing for Fragile X-Associated Disorders medical policy (policy number OCA 3.571) when applicable Plan criteria are met. Biochemical genetic tests used to study the amount or activity level of proteins to indicate changes to the DNA require prior authorization only when the test is included in the Applicable Coding section of a Plan genetic testing medical policy. See the following Plan medical policies for applicable prior authorization guidelines for molecular and chromosomal genetic testing types genetic testing available at [www.bmchp.org](http://www.bmchp.org) for BMC HealthNet Plan members (or at [www.SeniorsGetMore.org](http://www.SeniorsGetMore.org) for Senior Care Options members) and [www.wellsense.org](http://www.wellsense.org) for Well Sense Health Plan members:

1. **Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies**, policy number OCA 3.573
2. **Gene Expression Profiling of Tumor Tissue to Predict Cancer Recurrence and Risk Stratification (Including Oncotype DX™ and Other Tests)**, policy number OCA 3.572
3. **Genetic Testing for Familial Malignant Melanoma**, policy number OCA 3.78
4. **Genetic Testing for Fragile X-Associated Disorders**, policy number OCA 3.571
5. **Genetic Testing Guidelines and Pharmacogenetics**, policy number OCA 3.727
6. **Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome**, policy number OCA 3.57
7. **Genetic Testing for Hereditary Thrombophilia**, policy number OCA 3.728
8. **Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Pre-Genetic Screening)**, policy number OCA 3.726

**Description of Item or Service**

**Cologuard™**: A combined stool DNA and occult blood test (developed by Exact Sciences Corp.) approved by the U.S. Food and Drug Administration (FDA) to screen for colorectal cancer. The test includes both a hemoglobin immunoassay and molecular assays to screen for the presence of known DNA alterations during colorectal carcinogenesis in tumor cells sloughed into stool (testing for KRAS mutations, aberrant NDRG4 and BMP3 methylation, and ACTB). In August 2014, the FDA approved Cologuard™ for primary screening for colorectal cancer.

[DNA Testing of Stool Samples with Cologuard™ to Screen for Colorectal Cancer](#)
Deoxyribonucleic Acid (DNA) Testing of Stool Samples/Fecal DNA Testing to Screen for Colorectal Cancer: Screening test to detect colorectal cancer (CRC) based on the presence of specific, cancer-associated DNA mutations isolated from stool samples. Aberrant cells are shed from precancerous or cancerous lesions in the colon and rectum into the feces and DNA from the aberrant cells can be extracted for mutation testing. Examples of stool DNA tests used to screen for colorectal cancer but are no longer marketed include PreGen-Plus™ (by LabCorp. and Exact Sciences Corp.) and ColoSure™ (by LabCorp.). Fecal DNA testing is intended as first-line screening test for CRC in asymptomatic individuals with an average risk of developing colorectal cancer.

Medical Policy Statement

DNA testing of a stool sample as a first-line screening for colorectal cancer is considered medically necessary when ALL of the following criteria are met, as specified below in items 1 through 5:

1. The member is age 50 to 85 years old on the date of service; AND

2. Cologuard™ will be used as a first-line screening for colorectal cancer with DNA testing of a stool sample; AND

3. Cologuard™ cancer screening will be conducted no more than once every three (3) years for the member; AND

4. The member is asymptomatic (with no signs or symptoms of colorectal disease)∞ and ALL of the following criteria are met, as specified below in items a through d:
   a. Member has NO unexplained change(s) in bowel habits, such as diarrhea, constipation, or narrowing of stool, that lasts for more than a few days; AND
   b. Member has NO rectal bleeding, dark stools, or blood in stool; AND
   c. Member has NO unexplained cramping or abdominal pain; AND
   d. Member has NO unexplained weakness and fatigue; AND

∞ Note: These symptoms may be caused by conditions other than colorectal cancer including but not limited to infection, hemorrhoids, or inflammatory bowel disease.

5. The member has an average risk of developing colorectal cancer (as defined in the Definitions section of this policy) and ALL of the following criteria are met, as specified below in items a through d:
   a. Member has NO personal history of adenomatous polyps and/or serrated polyps; AND

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b. Member has NO personal history of colorectal cancer; AND

c. Member has NO personal history of inflammatory bowel disease; AND

d. Member has NO known biological family history of colorectal cancers or adenomatous polyps (with biological family defined as first-degree, second-degree, and third-degree relatives); Ł AND

Ł Note: Inherited syndromes associated with colorectal cancer (and categorized as high-risk syndromes) include familial adenomatous polyposis (FAP), attenuated familial adenomatous polyposis (AFAP), Lynch syndrome (hereditary nonpolyposis colorectal cancer or HNPCC), Turcot syndrome, Peutz-Jeghers syndrome, juvenile polyposis syndrome, serrated polyposis syndrome (SPS), and MUTYH-associated polyposis. A family history of adenomatous polyps is linked to a higher risk of colorectal cancer.

It is recommended that members at moderate or high-risk for colorectal cancer (CRC) be screened for colorectal cancer with an alternative cancer detection test such as colonoscopy (rather than Cologuard™ or an alternative fecal DNA screening test). According to a Hayes, Inc. safety assessment of Cologuard™, “A significant concern regarding the use of Cologuard for CRC screening is the possibility of a false-negative result, which may result in missed malignancies and a significantly reduced likelihood of survival (Levin et al., 2008).” **This safety concern related to Cologuard™ applies to members with average, moderate, or high-risk for developing colorectal cancer.**

Recommendations for colorectal cancer screening will vary by member age, risk category (average, moderate, or high risk), frequency of testing, and methods of screening. The Plan recommends that the treating provider utilize industry-standard guidelines for colorectal screening that are appropriate for the member. Clinical recommendations for colorectal cancer screening have been issued by the following professional organizations: American College of Gastroenterology, American College of Physicians, National Comprehensive Cancer Network, U.S. Preventive Services Task Force, and joint guidelines developed by the American Cancer Society, U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology.

Review the Plan’s Prior Authorization/Notification Requirements matrix for a list of services that require prior authorization; in addition, review the Plan’s Prior Authorization CPT/HCPCS Code Look-up Tools for the prior authorization requirement for each of the applicable, industry-standard billing codes for the requested service. The prior authorization matrix, code look-up tools, Plan medical policies, Plan reimbursement policies, and the member’s applicable benefit documents are available at [www.bmchp.org](http://www.bmchp.org) for BMC HealthNet Plan members and [www.wellsense.org](http://www.wellsense.org) for Well Sense Health Plan members.
Limitations

1. The use of Cologuard™ as a first-line screening test for a member with an average risk of colorectal cancer is considered medically necessary when all Plan medical criteria are met, as specified in the Medical Policy Statement section of this policy. Other types of fecal DNA screening tests for members with an average risk of colorectal cancer are considered experimental and investigational and will require Plan Medical Director review. The use of Cologuard™ is considered experimental and investigational when all criteria in the Medical Policy Statement section are NOT met and will also require Plan Medical Director review.

Requests submitted for Plan Medical Director review must include the following documentation from the treating provider: Medical record documentation verifying that the member has an average risk for colorectal cancer, verification of the clinical validity and clinical utility of the requested test for colorectal cancer screening for the member’s age and risk category, clinical practice guidelines from a professional society or the National Comprehensive National Comprehensive Cancer Network (NCCN) documenting the use of the requested test for the specified indication, and verification that the test will be utilized according to the FDA-approved intended use and ended indication(s).

2. The use of Cologuard™ or any other type of fecal DNA analysis used to screen members with a moderate or high risk of colorectal cancer (or when medical necessity criteria are not met, as specified in the Medical Policy section of this policy) is considered experimental and investigational and will require Plan Medical Director review.

Requests submitted for Plan Medical Director review must include the following documentation from the treating provider: Medical record documentation of the member’s risk for colorectal cancer, verification of the clinical validity and clinical utility of the requested test for colorectal cancer screening for the member’s age and risk category, clinical practice guidelines from a professional society or the National Comprehensive National Comprehensive Cancer Network (NCCN) documenting the use of the requested test for the specified indication, verification that the test will be utilized according to the FDA-approved intended use and indication(s), and clinical rationale for fecal DNA analysis as the most appropriate modality for the member at moderate or high risk for colorectal cancer (as an alternative to other testing such as colonoscopy or flexible sigmoidoscopy).

Refer to the Plan policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. See Plan policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. Review the Plan’s medical policy, Genetic Testing for Hereditary Colorectal Cancer (policy number OCA 3.64), rather than this policy for genetic mutation testing for hereditary colorectal cancer. See Plan policy, Genetic Testing Guidelines and Pharmacogenetics, policy number
OCA 3.727, for Plan genetic testing guidelines not outlined in this policy, including but not limited to predicting effectiveness of treatment, whole exome sequencing, and whole genome sequencing.

**Definitions**

**Adenomatous Polyp:** An area where normal cells that line the inside of a person’s colon begin to make mucous and form a mass on the inside of the intestinal tract.

**Attenuated Familial Adenomatous Polyposis (AFAP):** Type of polyposis syndrome caused by an autosomal dominant trait that carries a high risk for the development of colorectal cancer. The condition is characterized by fewer adenomatous polyps in the colon and rectum than in classic familial adenomatous polyposis (FAP). AFAP is a variant (subtype) of FAP, but AFAP has fewer than 100 adenomatous colorectal polyps (with 30 being the average) and generally has a later age of onset than FAP (i.e., 55 years of age or older, although polyps may develop as early as the late teens). Both AFAP and FAP are associated with genetic mutations of the adenomatous polyposis coli or APC gene (normally a tumor suppressor gene) on chromosome 5q21. (See the definition for familial adenomatous polyposis [FAP].)

**Average Risk of Colorectal Cancer:** The National Comprehensive Cancer Network (NCCN) defines average risk for colorectal cancer as an individual 50 years of age or older; has no personal, medical history of adenoma, sessile serrated polyp (SSP), or colorectal cancer (CRC); has no personal medical history of inflammatory bowel disease; and has a negative family history for CRC. The NCCN modality and schedule for colorectal cancer screening include:

1. Colonoscopy with rescreening with any modality in 10 years with no polyps (and polypectomy and necessary follow-up if polyps detected); OR

2. Fecal DNA testing or stool-based high-sensitivity guaiac-based or immunochemical-based testing; OR

3. Flexible sigmoidoscopy (with or without interval guaiac-based or immunochemical-based testing at year 3) with rescreening with any modality in 5 to 10 years when negative stool test and no polyps (and necessary follow up if polyps detected or positive stool test); OR

4. CT colonography with rescreening with any modality in 5 years with no polyps (and necessary follow up if polyps detected).

(Source: NCCN Guideline for Colorectal Cancer Screening, Version 2.2016.)

**Familial Adenomatous Polyposis (FAP or Classical FAP):** A type of hereditary polyposis syndrome caused by an autosomal dominant trait that carries a high risk for the development of colorectal cancer. The condition is characterized by a young age of onset (mid-teens, age 12-15 years old). The individual develops multiple (> 100) adenomatous colon polyps that carry a high risk for the
Development of colorectal cancer. More than 95% of people with FAP will have multiple colon polyps by age 35. If FAP is not recognized and treated, there is almost a 100% chance that a person will develop colorectal cancer; the risk of colon cancer is 87% by age 45. Classic FAP is one of the most clearly defined and well understood of the inherited colon cancer syndromes, equally affecting all genders. Both AFAP and FAP are associated with genetic mutations of the adenomatous polyposis coli or APC gene (normally a tumor suppressor gene) on chromosome 5q21. Approximately 20% to 30% of FAP cases are caused by new mutations, meaning that an APC germline mutations may be present in an individual even if it is absent in both parents. (See the definition for attenuated familial adenomatous polyposis [AFAP].)

**First Degree Relative:** A blood relative of an individual who shares approximately 50% of the individual’s genes defined as a biological parent, full sibling, or biological child.

**Genetic Blood Tests, Saliva Tests, or Buccal Swabs for Hereditary Colorectal Cancer:** A sample is tested to check for specific changes (mutations) in genes that help control normal cell growth, including the APC, EPCAM, MLH1, MSH2, MSH6, and PMS2 genes, to determine if an individual has an increased susceptibility to Lynch syndrome (previously known as hereditary nonpolyposis colorectal cancer or HNPCC), familial adenomatous polyposis (FAP), attenuated familial adenomatous polyposis (AFAP), or mutY homolog (MUTYH)-associated polyposis (MAP). See the Plan’s [Genetic Testing for Hereditary Colorectal Cancer](#) medical policy (policy number OCA 3.64) rather than this policy for medical necessity criteria for genetic testing to diagnose hereditary colorectal cancer.

**Genetic Tumor Tissue Tests for Hereditary Colorectal Cancer:** Tissue specimens of colorectal cancer tumor are analyzed to identify specific gene mutations, diagnosis a hereditary colorectal cancer syndrome (e.g., Lynch syndrome), and customize the individual’s care management strategy based on the diagnosis. See the Plan’s [Genetic Testing for Hereditary Colorectal Cancer](#) medical policy (policy number OCA 3.64) rather than this policy for medical necessity criteria for genetic testing to diagnose hereditary colorectal cancer.

**Genetic Testing:** According to U.S. Library of Medicine, genetic testing is defined as a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person’s chance of developing or passing on a genetic disorder. More than 1,000 genetic tests are currently in use, and more are being developed. Several methods can be used for genetic testing:

1. Molecular genetic tests (or gene tests) study single genes or short lengths of DNA to identify variations or mutations that lead to a genetic disorder.

2. Chromosomal genetic tests analyze whole chromosomes to see if there are large genetic changes, such as an extra copy of a chromosome or missing DNA, that cause a genetic condition.
3. Biochemical genetic tests study the amount or activity level of proteins; abnormalities in either can indicate changes to the DNA that result in a genetic disorder.

**Hereditary Polyposis Syndrome/Hereditary Mixed Polyposis Syndrome:** A genetic condition that is associated with an increased risk of developing polyps (cancerous and/or noncancerous) in the digestive tract. Examples of hereditary polyposis syndromes that are associated with increased risk of hereditary colorectal cancer include attenuated familial adenomatous polyposis (AFAP), familial adenomatous polyposis (FAP), and MYH-associated polyposis (MAP).

**Immunohistochemistry (IHC):** IHC testing uses special dyes to stain tissue samples. The presence or absence of staining indicates whether certain proteins are present in the tissue and identify which mutated genes caused the cancer. (This is one of the two main initial tests performed on colorectal cancer tissue specimens to identify individuals who might have Lynch syndrome.)

**Inflammatory Bowel Disease (IBD):** A group of chronic intestinal idiopathic diseases caused by dysregulated immune response to host intestinal microflora and characterized by inflammation of the large or small intestine. Symptoms of IBD include abdominal pain and diarrhea. The disease can be limited to the intestine or affect the skin, joints, spine, liver, eyes, and other organs. The two (2) major types of IBD are ulcerative colitis (limited to colon) and Crohn’s disease. There is genetic predisposition for IBD, and individuals with IBD have a higher risk of developing a malignancy.

**Lynch Syndrome:** Previously termed hereditary nonpolyposis colorectal cancer (or HNPCC), Lynch syndrome is the most common form of hereditary colorectal cancer. The syndrome is caused by an autosomal dominant trait, accounting for 2% to 4% of all colorectal cancer cases. Lynch syndrome is associated with a mutation in one of the mismatch repair mechanism (MMR) genes (i.e., MLH1, MSH2, MSH6, and/or PMS2). Defects in DNA mismatch repair result in microsatellite instability (MSI). MLH1 and MSH2 germline pathogenic variants account for approximately 90% of pathogenic variants in families with Lynch syndrome; MSH6 pathogenic variants in about 7%-10%; and PMS2 pathogenic variants in fewer than 5%. Germline deletions in EPCAM (not a mismatch repair gene) inactivate MSH2 in about 1% of individuals with Lynch syndrome and therefore such deletions are associated with Lynch syndrome. Recent evidence has shown that three deletions in the EPCAM gene are an additional cause of Lynch syndrome. Individuals with MLH1 and MSH2 gene mutations are often diagnosed with Lynch syndrome before age 50. Individuals with mutation of the MSH6 gene may have colorectal cancer diagnosed later in life, or over age 50. Other possible associated genetic mutations with Lynch syndrome may be with the MLH3, PMS1, and EXO1 genes.

**MutY Homolog (MUTYH)-Associated Polyposis (MAP):** A type of hereditary polyposis syndrome caused by an autosomal recessive trait that carries a high risk for the development of colorectal cancer. Individuals with MAP tend to develop multiple adenomatous colon polyps during their lifetime and are likely to develop polyps and colorectal cancer at a relatively young age, in their 20s to 50s. People with MAP most often resemble the clinical picture of attenuated familial adenomatous polyposis (AFAP), but it has been reported in individuals with clinical symptoms that are consistent with classical familial...
adenomatous polyposis (FAP) and Lynch syndrome. Individuals with MAP have mutations in both of their mutY homolog (MUTYH) genes (i.e., autosomal recessive trait, one from each biological parent), but patients often have no family history of colon cancer or polyps including their biological parents (although siblings may or may not be affected); therefore genetic testing is used to identify at-risk individuals.

**Second Degree Relative:** A blood relative of an individual who shares approximately 25% of the individual’s genes defined as a biological grandparent, grandchild, aunt, uncle, nephew, niece, or half-sibling.

**Sessile Serrated Polyp (Sessile Serrated Adenoma):** Polyp that displays a lumen with a serrated or stellate architecture. Serrated polyps may or may not be benign. The current classification of serrated lesions of the large intestine includes: hyperplastic polyps, traditional serrated adenomas, and sessile serrated adenomas or polyps with or without cytologic dysplasia.

**Third Degree Relative:** A blood relative of an individual who shares 12.5% of the individual’s genes as defined as a biological first cousin, great grandmother, or great grandfather.

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines. Plan prior authorization is required for all genetic testing, even when the applicable code for the genetic test is not listed in a Plan policy.
**Clinical Background Information**

Colorectal cancer is the third most common cancer regardless of gender. Worldwide, an estimated 1.4 million cases of colorectal cancer occurred in 2012. About 693,900 deaths from colorectal cancer occurred in 2012 worldwide, accounting for 8% of all cancer deaths. Colorectal cancer may be sporadic, familial, or inherited.

Recommendations for colorectal cancer screening vary by member age, risk category, frequency of testing, and methods of screening. Guidelines for colorectal screening are issued by the following professional organizations: American College of Gastroenterology, American College of Physicians, National Comprehensive Cancer Network, U.S. Preventive Services Task Force, and joint guidelines developed by the American Cancer Society, U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology.

The National Comprehensive Cancer Network (NCCN) has developed colorectal cancer screening guidelines for average-risk and high-risk individuals. According to these NCCN clinical guidelines, screening for colorectal cancer is recommended for adults age 50 to 75 years old with an average risk of developing colorectal cancer. Recommended screening options include colonoscopy every 10 years; annual fecal-based tests (every 3 years with fecal DNA testing for individuals at average risk for colorectal cancer); flexible sigmoidoscopy every 5 to 10 years with or without interval guaiac-based or immunochemical-based testing at year 3; or CT colonography (virtual colonoscopy) every 5 years. Adjustments to NCCN screening protocols may be necessary based on the member’s individual risk, age, comorbidities, screening test results, and thoroughness of testing. Colonoscopy is indicated after abnormal findings from screening tests that include stool-based testing, flexible sigmoidoscopy, or CT colonography. Because the risk of colorectal screening increases with age, the decision to screening individuals between the ages of 76 to 85 should be individualized based on associated risks and benefits of testing. There are limited data on the use of Cologuard™ with individuals with a high risk for colorectal cancer. (Source: NCCN Guideline for Colorectal Cancer Screening, Version 2.2016.)

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) has implemented the following national coverage determinations (NCDs) related to genetic tests: NCD for Colorectal Cancer Screening Tests (210.3) for coverage of immunoassay and guaiac fecal occult blood tests and the Cologuard™ - Multitarget Stool DNA (sDNA) test when CMS applicable criteria are met, NCD for Pharmacogenomic Testing for Warfarin Response (90.1) for medically necessary indications for testing as determined by CMS, and NCD for Cytogenetic Studies (190.3) for coverage based on CMS guidelines. No CMS guidelines were identified for other fecal DNA tests to screen for colorectal cancer (except as stated above in NCD 210.3 for Cologuard™). Medicare uses a DNA Testing of Stool Samples with Cologuard™ to Screen for Colorectal Cancer

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combination of national and local coverage determinations for making coverage decisions for genetic tests. Medicare administrative contractors (MAC) may implement local coverage determinations (LCDs) that apply only within their own jurisdictions. Verify if applicable CMS criteria are in effect (through an NCD, LCD, or other CMS guidelines) for the specified genetic test, product name, site-specific gene analysis, and the indication for testing on the date of the prior authorization request for a Senior Care Options member.

References


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Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3). Effective Date October 9, 2014. Implementation Date September 8, 2015. Accessed at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&ncdver=5&CoverageSelection=Both&ArticleType=All&PpolicyType=Final&s=Massachusetts&KeyWord=colorectal+cancer&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAABAAAAAAA%3d%3d


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**Policy Revisions History**

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**Last Review Date**

04/01/17

**Next Review Date**

04/01/18

**Authorizing Entity**

MPCTAC

**Other Applicable Policies**

Medical Policy - Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies, policy number OCA 3.573
Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy - Gene Expression Profiling of Tumor Tissue to Predict Cancer Recurrence and Risk Stratification (Including Oncotype DX™ and Other Tests), policy number OCA 3.572
Medical Policy - Genetic Testing for Familial Malignant Melanoma, policy number OCA 3.78
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Medical Policy - Medically Necessary, policy number OCA 3.14
Medical Policy - Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Prenatal Screening), policy number OCA 3.726

**Reference to Applicable Laws and Regulations**


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Disclaimer Information: *

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

Massachusetts General Law. Chapter 111. Section 70G. (M.G.L. c. 111 sec. 70G.) Genetic information and reports protected as private information; prior written consent for genetic testing. Accessed at: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section70G