Geisinger Health Plan Policies and Procedure Manual

Policy: MP098

Section: Medical Benefit Policy

Subject: Genetic Testing Related to Colorectal Cancer

Applicable line of business:

Commercial	**x**	**Medicaid**	**x**
Medicare	**x**	**ACA**	**x**
CHIP	**x**		

I. Policy: Genetic Testing Related to Colorectal Cancer

II. Purpose/Objective:

To provide a policy of coverage regarding Genetic Testing Related to Colorectal Cancer

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Genetic testing related to colorectal cancer involves the analysis of DNA, RNA, chromosomes, proteins, and/or certain metabolites in order to detect heritable disease-related genotypes. This policy focuses primarily on testing for hereditary GI cancer risks. There are currently two well-defined categories of hereditary colorectal cancer syndromes: polyposis syndromes (includes familial adenomatous polyposis (FAP), MUTYH-associated polyposis (MAP), and other rare disorders) and hereditary nonpolyposis colorectal cancer syndrome, now called Lynch syndrome (LS).

Lynch syndrome accounts for approximately 3% of CRCs and 3% of endometrial cancers. APC-associated polyposis conditions historically accounted for about 0.5% of all CRC diagnoses; this figure is declining as more at-risk family members undergo successful treatment following early polyp detection and prophylactic colectomy.

Lynch Syndrome genetic testing includes the following genes: MLH1, MSH2, MSH6, PMS2, EPCAM. Sequential testing is only cost effective when directed by dMMR status on a tumor. Otherwise, it is not a cost-effective approach for evaluation of hereditary colon cancer syndromes.

Multi-gene panel testing (MGPT) is now the preferred strategy for evaluation of inherited cancer risk. Compared to genetic evaluation based on family history or tumor testing for evidence of mismatch repair deficiency, multi-gene panel testing has comparable or even higher yield for identifying individuals with Lynch syndrome. There is a higher yield for identifying individuals with a pathogenic variant in a cancer risk gene with known clinical actionability given shared phenotypes among hereditary cancer syndromes. Recent studies demonstrate a yield of 7.8% to 16.0% among patients with CRC diagnosed at any age.

Note: Germline MGPT should include at a minimum the following CRC risk-associated genes: APC, MUTYH, MLH1, MLH2, MSH6, PMS2, EPCAM, BMPR1A, SMAD4, PTEN, STK11.

INDICATIONS:
The Plan considers molecular susceptibility testing for hereditary colorectal cancer via panel testing, medically necessary in ANY of the following indications:

MEDICAL CRITERIA:

Lynch Syndrome:
Lynch syndrome (LS): (*MLH1, MSH2, MSH6, PMS2, EPCAM*) gene sequencing with deletion and duplication analysis is considered medically necessary for members who meet any **one** of the following criteria OR meets current NCCN Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric criteria:

- Colorectal or endometrial cancer at ≤50, regardless of MMR or MSI status.
- Colorectal or endometrial cancer >50 AND
    - MMR deficiency per IHC analysis, OR
    - MSI-high status in tumor tissue, OR
    - a pathogenic variant in a Lynch-related gene through next-gen sequencing in tumor tissue; OR
    - one or more close relatives with Lynch-related cancers diagnosed at any age.
- History of any solid tumor with evidence of mismatch repair deficiency (MMRd) or MSI-high status.
- Has been diagnosed with 2 or more Lynch Syndrome (LS)-associated tumors*, regardless of age; or
- Has no personal history of cancer, but has a family history of ANY of the following criteria:
    - ≥1 first-degree relative with a colorectal or endometrial cancer diagnosed <50 y
    - ≥1 first-degree relative with a colorectal or endometrial cancer and a synchronous or metachronous LS-related cancer regardless of age
    - ≥2 first-degree or second-degree relatives with LS-related cancers,regardless of age
    - Has family history of a close relative** with a molecular diagnosis of LS; OR
- Has ≥5% risk of LS on a validated mutation prediction model (eg, MMRpro, PREMM1,2,5, MMRpredict);

* Lynch syndrome-related cancers include colorectal, endometrial, gastric, ovarian, pancreas, ureter, bladder, and renal pelvis, biliary tract, brain, and small intestinal cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.

** Close relative is considered by the health plan to be a first or second degree relative. Half and full relatives are counted.

POLYPOSIS SYNDROMES

APC & MUTYH gene testing for familial adenomatous polyposis (FAP), attenuated familial adenomatous polyposis (AFAP), and MUTYH associated polyposis syndrome (MAP) is covered in ANY of the following situations:

1. >10 adenomatous colonic polyps in their lifetime; OR
2. A member has a close relative with a clinical or molecular diagnosis of FAP, aFAP, or MAP; OR
3. Personal history of desmoid tumor, hepatoblastoma, or cribriform-morular variant of papillary thyroid cancer OR
4. Colorectal cancer at any age with cumulative total of >5 adenomatous polyps OR
5. Two primary cancers with gastrointestinal or colorectal origin; OR
6. One or more upper GI polyps with the following histology: pyloric gland adenoma, gastric adenoma, or fundic gland polyps with high-grade dysplasia

RARE POLYPOSIS SYNDROMES

1. >2 hamartomatous polyps in their lifetime; OR
2. >5 serrated colonic polyps in their lifetime; OR
3. >5 polyps of mixed histologic types <40y

SMAD4 AND BMPR1A TESTING (Juvenile Polyposis Syndrome)

Genetic testing for SMAD4 and BMPR1A gene variants is considered medically necessary when any one of the following criteria is met:

1. A documented diagnosis of juvenile polyposis syndrome based on any one of the following:
    - at least 3 juvenile polyps in the colon; or
    - multiple juvenile polyps in other parts of the gastrointestinal tract; or
    - any juvenile polyps in a person with a known family history of juvenile polyps

    OR
2. Documentation of a close relative diagnosed with juvenile polyposis syndrome.

STK11 Testing (Peutz-Jeghers Syndrome)

Genetic testing for STK11 gene variants is considered medically necessary when any of the following criteria is met:
There is a known family history of STK11 (LKB1) gene mutation; or
The member has a clinical diagnosis of PJS based on as least TWO of the following features:

- Two or more histologically confirmed Peutz-Jeghers polyps of the small intestine
- characteristic mucocutaneous pigmentation of the mouth, lips, nose, eyes, genitalia, or fingers
- family history of Peutz-Jeghers syndrome

POLE and POLD1 Testing (Polymerase proofreading-associated polyposis (PPAP))

Genetic sequencing and deletion/duplication analysis for POLE and POLD1 genes is considered medically necessary when any of the following criteria is met:

- ≥10 cumulative adenomas; AND

- Prior *APC* and *MUTYH* testing has been completed and is negative or inconclusive.

Immunohistochemical (IHC) Analysis for Mismatch Repair (MMR)
Universal MMR-IHC MSI testing performed on tissue from the primary tumor is considered medically necessary for all members with newly diagnosed colorectal cancer. Emerging data suggest metastatic tissue produces concordant results and should be considered an acceptable alternative.

Microsatellite instability (MSI) Testing
MSI testing is medically reasonable and necessary for members with an unresectable or metastatic colorectal primary, either MSI or a multigene NGS or other multi-analyte methodology panel inclusive of minimum 5-8 MSI microsatellite loci

TUMOR GENOTYPING: KRAS, NRAS, BRAF
It is medically necessary for all members with newly diagnosed OR metastatic colorectal cancer to have tumor genotyping for RAS (KRAS and NRAS) and BRAF mutations individually via PCR or IHC, or as part of an NGS panel if individual testing is not available.

Related to Universal LS screening:
BRAF V600E is medically necessary when MLH1 OR MLH1/PMS2 are absent on MMR IHC studies to determine medical necessity for germline LS testing. MLH1 promotor hypermethylation testing is considered medically necessary after BRAF V600E testing has been completed and is negative, as the 3rd step in the algorithm to determine necessity for germline LS testing.

BRAF V600E testing is not indicated for use in endometrial cancers. MLH1 promotor hypermethylation should be performed ONLY if BRAF V600E is negative (absent).

COLOGUARD TESTING:

Fecal DNA Testing: (e.g., Cologuard,) **DOES NOT REQUIRE PRIOR AUTHORIZATION** a noninvasive, multitarget fecal DNA test for the qualitative detection of colorectal neoplasia-associated DNA markers in addition to the presence of occult hemoglobin in stool is covered as a preventive screening methodology once every 3 years according to the following criteria:

- Age 45 to 85 years; and
- Asymptomatic (no signs/symptoms including but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test, or fecal immunochemical test); and
- There has been no documentation of a normal colonoscopy in the previous 10 years; and
- At average risk of developing CRC defined as:
    - no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease including Crohn's disease and ulcerative colitis; and
    - no family history of colorectal cancer, adenomatous polyps, familial adenomatous polyposis (FAP / MAP), neurofibromatosis type 1, or Lynch syndrome,

Genetic testing is appropriate only when offered in a setting where a licensed or certified genetic counselor* or adequately trained health care professional is able to provide appropriate pre- and post-test genetic counseling, and medical necessity is supported by ALL of the following criteria:

1. The information is needed to adequately assess risk; and
2. The information will be used in the immediate care plan; and
3. Pedigree analysis establishes a high risk group for the disease; or
4. Clinical presentation of symptomology is evident and diagnosis cannot be established with conventional evaluation testing.

*A genetic counselor is considered by the Plan to be qualified if the following are met:

- M.S. or Ph.D. degree from a genetic counseling program approved/recognized by the American Board of Genetic Counseling or the American Board of Medical Genetics.

or

- Board certified or board qualified/eligible in the orderly process of obtaining board certification by the American Board of Genetic Counseling or American Board of Medical Genetics

and

- Proof of current competence and demonstrated ability (minimum of two years recent and continual experience within the past three years).

EXCLUSIONS:
There is no evidence to support the use of genetic testing for individuals from the general population with average risk. This is considered **NOT MEDICALLY NECESSARY.**

The ColonSentry testing panel is considered **experimental, investigational, or unproven** and **is NOT COVERED.** There are no current evidence-based guidelines from medical professional organizations or public health agencies that recommend ColonSentry for colorectal cancer screening and no evidence to support the use of this testing.

For Commercial and Medicaid Business Segments: The Epi proColon test is considered **experimental, investigational, or unproven** and is **NOT COVERED**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

For Medicare Business Segment: Epi proColon testing is covered as an alternative colorectal cancer screening strategy.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

PROCESS:
The Plan will utilize available published, peer reviewed medical literature, independent technology assessment program reports and/or review by the Geisinger Clinic Technology Assessment Committee to evaluate the following criteria when assessing the validity and efficacy of a specific genetic test:

- The analytical power of a test determined by its sensitivity and specificity is established.
- There is evidence of defined outcome measures that permits conclusions concerning the effect on health outcomes.
- The net health outcomes benefit of the test as compared to established alternatives is evaluated if applicable.
- The availability of test to membership is evaluated.
- The appropriate governmental and/or professional regulatory body approval is established.
- The test result will influence the treatment or alter the management of the member medical care plan.
- The test result has the capability to confirm a diagnosis when conventional medical evaluation is equivocal.

CODING ASSOCIATED WITH: Genetic Testing Related to Colorectal Cancer
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

81201 APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; FULL GENE SEQUENCE
81202 APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; KNOWN FAMILIAL VARIANTS
81203 APC (ADENOMATOUS POLYPOSIS COLI) (EG, FAMILIAL ADENOMATOSIS POLYPOSIS [FAP], ATTENUATED FAP) GENE ANALYSIS; DUPLICATION/DELETION VARIANTS
81288 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis
81435 Hereditary colon cancer syndromes (eg, Lynch syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2
81436 Hereditary colon cancer syndromes (eg, Lynch syndrome, familial adenomatosis polyposis); duplication/deletion gene analysis panel, must include analysis of at least 8 genes, including APC, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, and MUTYH
81525 ONCOLOGY (COLON), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR

OF 12 GENES (7 CONTENT AND 5 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS A RECURRENCE SCORE

81528 Fecal DNA Test- Cologuard

81210 BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant

81292 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis

81293 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants

81294 MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants

81295 MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis

81296 MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants

81297 MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants

81298 MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis

81299 MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants

81300 MSH6 (mutS homolog 6 [E. coli]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants

81301 Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed

81309 PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha)(eg. colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7,9, 20)

81317 PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis

81318 PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants

81319 PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants

81327 Sept9 (septin 9) (eg, colorectal cancer) methylation analysis

0101U Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrom, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sangar, MLPA, and array CGH, with MRNA analytics to resolve v

0155U (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha)(eg. colorectal and breast cancer) gene analysis,

0157U APC (APC regulator of WNT signaling pathway)(EG,familial adenomatosis polyposis [FAP] MRNA sequence analysis (list seperately in addition to code for primary procedure

0158U MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)

0159U MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)

0160U MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)

0161U PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis

0162U Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2)

0163U Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas (new code effective 4/1/20) (BeScreened™-CRC)

0235U PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions

0238U Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions

0261U Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score (Immunoscore®)
0368U Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer
0421U Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk New 2024
0453U Oncology (colorectal cancer), cell-free DNA (cfDNA), methylation-based quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA) *{ColonAiQ}*
0491U Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker-expressing cells, peripheral blood
0492U Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of PD-L1 protein biomarker-expressing cells, peripheral blood
0496U Oncology (colorectal), cell-free DNA, 8 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported positive or negative for colorectal cancer or advanced adenoma risk
0498U Oncology (colorectal), next-generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation
0499U Oncology (colorectal and lung), DNA from formalin-fixed paraffin-embedded (FFPE) tissue, next-generation sequencing of 8 genes (NRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection
0501U Oncology (colorectal), blood, quantitative measurement of cell-free DNA (cfDNA)

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/03

Revised: 7/23/04(criteria); 6/05 (update Bethesda criteria); 6/06; 6/07(revised criteria); 6/09 (coding); 6/10 (updated criteria); 8/12, 11/14 (Added medicare, Medicaid, healthy PA for Fecal DNA), 11/15 (added exclusion); 5/16 (expanded coverage for fecal DNA testing); 11/16 (remove PA for fecal DNA screening test); 4/17 (clarified criteria), 4/18 (criteria update); 7/19 (add Medicare Epi proColon coverage), 11/19 (update Cologuard age recommendation); 11/20 (add gene variants and criteria), 11/21 (revise Lynch, IHC and MSI criteria) , 12/22 (revised criteria to meet current NCCN recommendations); 11/23 (revised criteria, removed prior auth) 11/24(Revise LS criteria, and polyposis criteria)

Reviewed: 7/08, 1/11, 1/12, 8/13, 8/14, 4/19

CMS UM Oversight Committee Approval: 12/23, 12/24