KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Genetic Panels using Next Generation Sequencing (germline/blood testing, excluding Advanced Cancer)

Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage).

Prevention and Invitae Corporation are the preferred labs for genetic testing, when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae*

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions
For the NGS testing for Advanced Cancer, see below:

- ***Next Generation Sequencing for Advanced Cancer***

Related Policies:

Genetic Screening and Testing
Pharmacogenomic Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Next Generation Sequencing (NGS) (90.2) (Applies to diagnostic lab tests using NGS for somatic (acquired) and germline (inherited) breast and ovarian cancer.) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) ***FDA-approved tests*** *(not all-inclusive)* FoundationFocus™ CDxBRCA Assay (Foundation Medicine, Inc.) FoundationOne CDx (Foundation Medicine, Inc.) FoundationOne Liquid CDx (Foundation Medicine, Inc.) Guardant360® CDx (Guardant Health, Inc.) Oncomine™ Dx Target Test (Thermo Fisher Scientific, Inc.) Praxis™ Extended RAS Panel (Illumina, Inc.)

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	MSK-IMPACT™ (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets))
Local Coverage Determinations (LCD)	9/30/2015 - Noridian retired LCD for Genetic Testing (L24308). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. MolDX: Next-Generation Sequencing for Solid Tumors (L38121) (Applies to diagnostic lab tests using NGS for solid tumors.)

General Coverage Rules – LCD 24308

1. Genetic tests for cancer are only a covered benefit for a beneficiary with a personal history of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured. Genetic testing is considered a non-covered screening test for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules. For example, Medicare does not cover genetic tests based on family history alone.

3. A covered genetic test must be used to manage a patient. Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).

5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:

The MolDX Program has determined certain gene tests do not meet Medicare's medical necessary requirements, and that the inclusion of these genes will result in an entire panel to be denied. MolDX has determined that testing for the below genes is a statutorily excluded service. Unless indicated otherwise, panels that include these genes will be denied. Please see the individual Test Coding and Billing Guidelines for each gene.

Palmetto GBA is the Medicare contractor for Molecular Diagnostic Testing – this site has the most up to date Medicare coverage guidelines for genetic testing.
MolDX® Program (Administered by Palmetto GBA)

Local Coverage Decisions (LCD)/Articles (LCA) *not all-inclusive – refer to the MolDX® Program link above*

ID	Title	Codes *(not all-inclusive)*

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L36163	8/20/2022 Noridian retired LCD MolDX: BRCA1 and BRCA2 Genetic Testing. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L38974 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer.	81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217, 81432, 81445, 81455, 0102U, 0103U, 0129U
L36386	MolDX: Breast Cancer Assay: Prosigna	81520
L37824	MolDX: Breast Cancer Index® Gene Expression Test	81518
L36186	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	81206, 81207, 81208, 81219, 81450, 0027U
L36159	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)	81240, 81241, 81291
L36374	8/20/2022 Noridian retired LCD MolDX: Genetic Testing for Lynch Syndrome. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L38974 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer.	81210, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81301, 81317, 81318, 81319, 81433, 81435, 81436, 0101U
L36192	MolDX: MGMT Promoter Methylation Analysis	81287
L36544	MolDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36544) **not covered per LCD*	81383
L36256	MolDX: Molecular Diagnostic Tests (MDT)	*See LCA: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)
L38333	MolDX: Blood Product Molecular Antigen Typing	0001U, 0084U
L36329	08/08/2022 Noridian retired LCD MolDX: ConfirmMDx Epigenetic. Molecular Assay. MolDX: Genetic Testing for Lynch Syndrome. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L39007MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer.	81551, 81313 Billing and Coding: MolDX: Molecular Biomarkers to Risk Stratify Patients at Increased Risk for Prostate Cancer

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L38341	MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease *(Decipher and similar, i.e., Prolaris)*	81541, 81542
L36339	MolDX: NRAS Genetic Testing	81311, 81479
L36557	01/01/2018 Noridian retired LCD MolDX: Chromosome 1p/19q Deletion Analysis (L36557). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36557 for determining medical necessity, along with L36256 MolDX: Molecular Diagno2stic Tests (MDT).	
L36891	MolDX: Percepta© Bronchial Genomic Classifier	81479

For Non-Medicare Members

Kaiser Permanente considers genetic testing panels medically necessary when the results are expected to directly affect treatment, management, surveillance or reproductive decisions and when all genes or genetic variants included in the panel have high quality, evidence-based guidelines established to direct clinical management based on results.

Testing for individual components of a panel may be medically necessary in some clinical situations. Separate clinical criteria for these components may apply.

Members must meet ALL the following criteria:

1. The member is at clinical risk for a genetic condition because of current documented symptoms being displayed or a strong family history of the condition.
2. The test is scientifically valid and can be adequately interpreted.
3. The results will directly affect a member's clinical management or reproductive decisions.
4. After appropriate clinical work-up, and informed consent by the appropriate practitioner, the genetic test is indicated.

Genetic testing is not covered for the medical management of a family member who does not have Kaiser Permanente coverage.

1.) If Kaiser Permanente Clinical criteria for BRCA genetic testing using MCG* A-0499 are met AND
   a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
   b. One of the following NGS panels can be covered:
      i. Invitae Breast Cancer STAT Panel
      ii. Invitae Breast Cancer Guidelines – Based Panel
      iii. Invitae Breast and Gynecological Cancers Guidelines – Based Panel
      iv. Prevention – Breast Cancer- High Risk Panel

2.) If Kaiser Permanente Clinical Review Criteria for Lynch syndrome genetic testing using MCG* A-0533 are met AND
   a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
   b. One of the following NGS panels can be covered:
      i. Invitae Lynch Syndrome Panel
      ii. Invitae Colorectal Cancer Guidelines – Based Panel
      iii. Prevention Lynch Syndrome Panel

3.) If Kaiser Permanente Clinical Review Criteria for both BRCA and Lynch syndrome genetic testing are met

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a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
b. The following NGS panel can be covered
    i. Invitae Breast and Gynecological Cancers Guidelines – Based Panel
    ii. Prevention Hereditary Breast and Ovarian Cancer – High Risk and Lynch Syndrome Panel

***If a member has had prior negative BRCA1 & 2 gene testing:** In most cases, further genetic testing would not be considered necessary. However, in cases where there is a very strong personal or family history suggesting a genetic disposition, testing for additional evidence-based cancer susceptibility genes is warranted. One of the Invitae NGS panels listed in section 1b above could be covered.

Criteria for other Genetic Panel Tests:
Refer to the Genetic Screening and Testing clinical review criteria to see information about review criteria for specific genetic tests *not* described above; please also check Invitae Test Catalog or Prevention Test Catalog

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

*MCG are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following genetic panels are **not considered medically necessary** because the current scientific evidence is not yet sufficient to establish how test results from all components of these panels should be used to direct treatment decisions. There is also insufficient evidence to establish that use of these genetic panels to guide treatment decisions results in improved patient health outcomes.

This list is not all-inclusive as new genetic panel tests are frequently being developed.

Test	Laboratory
BRCANext™ or BRCANext-Expanded™	Ambry Genetics™
BROCA Cancer Risk Panel	University of Washington
CancerNext™ or CancerNext-Expanded™	Ambry Genetics™
ColoNext™	Ambry Genetics™
Cell Search	Veridex
ColoSeq™	University of Washington
Comprehensive Mitochondrial Nuclear Gene Panel	GeneDx
Counsyl™ Panel	Counsyl Genomics
Cxbladder	Pacific Edge Laboratory
DetoxiGenomic®	Profile Test Genova®
FirstStepDx PLUS©	Lineagen
FoundationOne™	Foundation Medicine, Inc.
Galleri®	Grail, Inc
Gene Trails AML/MDS Genotyping Panel	Oregon Heath & Science Univ
Gene Trails NSCLC Genotyping Panel	Oregon Heath & Science Univ
Gene Trails Solid Tumor Panel	Oregon Heath & Science Univ
Genomind Professional PGx Express	Genomind, Inc.
GeneSight® Psychotropic test	Myriad®
Guardant360 CDx	Guardant Health
Leigh Syndrome Nuclear Gene Panel	GeneDx
Monogenic Hypertension Evaluation Panel	Athena Diagnostics

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Test	Laboratory
myRisk® Hereditary Cancer Panel	Myriad®
Horizon™ Advanced Carrier Screening	Natera, Inc.
PancNext™	Ambry Genetics™
Prometheus IBD sgi® Diagnostic (Serology)	Prometheus Laboratories
Anser TM ADA for Adalimumab (Humira) Antibodies Anser TM IFX test for Infliximab (Remicade) Antibodies	Prometheus Laboratories See the Medical Policy "Prometheus Lab Testing"
OncotypeDx Genomic Prostate Score **MCG* A-0712**	Genomic Health
Proteomics – Ovarian Cancer Markers (OVA1) **MCG* A-0709**	
Proteomics – Prostate Cancer Markers	
Providence Personalized Medicine Panel, Solid Tumor (ProvSeq 523)	Providence Health and Services - Oregon
RenalNext®	Ambry Genetics™
Signatera™	Natera™
CancerTYPE ID®	Biotheranostics
Vascular Aneurysm Genetic Panel	University of Washington
NeurodevelopmentNext™	Ambry Genetics™
X-linked Intellectual Disability Panel	NTD Genetics
X-linked Intellectual Disability Sequencing Panel	Greenwood Genetic Center
Tempus xG Hereditary Cancer Panel	Tempus labs

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The emergence of new genetic testing technology, including next generation sequencing and chromosomal microarray, has made possible the ability to examine many genes simultaneously. This in turn has resulted in a proliferation of new genetic testing panels. The intended use for these panels varies.

For example, for hereditary disorders, a clinical diagnosis may already be established, in which case genetic testing is performed to determine the specific causative mutation and a diagnostic genotype. In other cases, the clinical findings may suggest a number of possible etiologies, in which case genetic testing is performed in the hope of making a specific diagnosis.

For cancer panels, intended uses also differ. Some panels may be intended to identify the presence of a hereditary syndrome predisposing to the development of certain cancers. Other panels look for somatic mutations in a tumor biopsy specimen with the intent of identifying a cancer's primary site of origin and/or identifying a molecular target to help in selecting treatment.
Panels using next generation sequencing technology are currently available in the areas of cancer, cardiovascular disease, neurologic disease, and for prenatal testing and screening. These panels are intuitively attractive to use in clinical care because they can analyze multiple genes quickly and may lead to greater efficiency in the work-up of genetic disorders. It is also possible that in some cases these "bundled" gene tests can be performed more cost efficiently than individual sequencing, although this may not be true in all cases.

On the other hand, the use of newer sequencing techniques is associated with a higher rate of results which may be of uncertain clinical significance and/or for which there are no reliable evidence-based guidelines regarding management or surveillance. This can potentially lead to unnecessary follow-up testing and procedures, which have their own inherent risks and cost.

The design and composition of genetic panel tests are not standardized. The make-up of each panel is determined by the specific laboratory that has developed the test. In addition, the composition of any individual panel is likely to change over time, as new genetic variations are discovered and added to the existing panels.

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Evidence and Source Documents

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)
Coloseq ™ Colon Cancer Panel

Medical Technology Assessment Committee (MTAC)

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)

BACKGROUND

Understanding the underlying genetic contribution to cancer can give insight to individual and familial risk. This is especially important with hereditary cancer since risk-reducing strategies for additional primary cancers can vary based on molecular diagnosis. Identifying an underlying genetic cause can also aid in the diagnostic process since relying on family history alone can be challenging. Numerous genetic mutations are associated with certain types of hereditary cancer. Traditionally, Sanger sequencing has been considered the gold standard in mutation detection and is still the method of choice for most diagnostic labs. However, since multiple genes are implicated in each type of cancer, testing by traditional sequencing can be burdensome and expensive. Advancements in sequencing technologies have made it possible to generate a large amount of data quickly and cost effectively (Choi, Scholl et al. 2009). Next generation sequencing (NGS) provides investigators with the required capacity to analyze large panels of genes or whole genomes in a single run (panel testing) (Previati, Manfrini et al. 2013). As a result, these technologies are enabling new tailor-made approaches to diagnostic testing with an increasing number of commercially available genetic panels (Walsh, Lee et al. 2010; Michils, Hollants et al. 2012). Ambry Genetics offers four different genetic testing panels for hereditary cancers (Keiles 2013). These panels address three specific types of cancer that may be inherited including breast, ovarian and colorectal. The mutations included in these panels are associated with varying levels of risk of developing cancer, and only some of the mutations are associated with well-defined cancer syndromes which have established clinical management guidelines (Burke, Petersen et al. 1997).

TABLE 1: PANEL NAME AND DESCRIPTION

PANEL NAME	DESCRIPTION
BreastNext™	Next-generation sequencing panel that simultaneously analyzes 16 genes that contribute to increased risk for breast cancer including BRCA1 and BRCA2.
OvaNext™	Next-generation sequencing panel that simultaneously analyzes 21 genes that contribute to increased risk for breast ovarian and/or uterine cancers.
Colonext™	Next-generation sequencing panel that simultaneously analyzes 14 genes that contribute to increased risk for colon cancer.
CancerNext™	Next-generation sequencing panel that simultaneously analyzes 24 genes that contribute to increased risk for breast colon, ovarian, uterine and other cancers.

There is no standardization to the make-up of genetic panels. Composition of the panels is variable, and different commercial products for the same condition may test a different set of genes. The make-up of the specific panels is determined by the specific lab that has developed the test. In addition, the composition of any individual panel is likely to change over time, as new mutations are discovered. The majority of cancer panel tests are laboratory derived tests that are not subject to U.S. Food and Drug Administration (FDA) approval. Labs are subject to Clinical Laboratory Amendment (CLIA) regulations that monitor high-complexity testing.

10/21/2013: MTAC REVIEW

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)

Evidence Conclusion: Analytic Validity According to Ambry Genetics, the analytic sensitivity for the 22 genes analyzed on their cancer susceptibility panels by next generation sequencing is 96-99% (Keiles 2013), however, no publications were found to support these claims. No published literature addressed the analytic validity of the Ambry Genetics' Next-Gen Cancer Panels. Clinical Validity While it may be possible to evaluate the clinical validity of sequencing of individual genes found on these panels, the clinical validity of Ambry Genetics' Next-Gen Cancer Panels, which include mutations associated with unknown or variable cancer risk, is uncertain. No published literature addressed the clinical validity of panel testing for cancer susceptibility with NGS. Clinical Utility Theoretically, identifying an individual with a genetic mutation that indicates a high risk of developing cancer could lead to changes in clinical management and improved health outcomes including modifications in cancer surveillance and treatment guidance. However, identifying mutations that have intermediate or low risk of developing cancer is of limited clinical utility. With potential harms, such as psychological stress and unnecessary prophylactic intervention, the management for patients found to have one of these mutations is not well defined. No published literature addressed the clinical utility of the Ambry Genetics' Next-Gen Cancer Panels. Conclusion

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There is insufficient evidence to determine the analytic validity, clinical validity or clinical utility of the Ambry's Next-Gen Cancer Panels.

Articles: A search of PubMed was completed for the period through August 2013 for studies on the accuracy of NGS for predicting risk of hereditary breast ovarian and colon cancer. The search strategy used the terms *next generation, cancer panel, BreastNext, breast cancer, ColoNext, colon cancer, OvaNext, ovarian cancer and CancerNext* with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Articles were limited to those published in the English language with human subject enrollment. The search was supplemented by an examination of article bibliographies in addition to the PubMed *related* articles function.

The use of Ambry next generation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Coloseq™ Colon Cancer Panel

BACKGROUND

Approximately 2% to 5% of colorectal cancer (CRC) can be attributed to inherited syndromes such as Lynch syndrome (also known as hereditary non-polyposis colon cancer), familial adenomatous polyposis (FAP), and MUTYH-associated polyposis. Patients with these syndromes are at higher risk for CRC and, therefore, require more intensive surveillance programs. Lifetime CRC risk is 50-80% for patients with Lynch syndrome, 100% for patients with FAP, and 80% for patients with MUTYH-associated polyposis compared to 5-6% for patients without these syndromes (Kaz and Brentnall 2006; Jasperson, Tuohy et al. 2010). There are several different strategies used to identify families at high-risk for developing these syndromes, however, genetic testing is the gold standard for diagnosing Lynch syndrome and FAP. To date, clinical diagnostic criteria for MUTYH- associated polyposis have not been fully established; however, genetic testing may be warranted in individuals with more than 10 colorectal adenomas who are negative for APC mutations (Jasperson, Tuohy et al. 2010). Genetic testing of high-risk families allows for a more accurate diagnosis and more specific targeting of clinical screening and surveillance protocols to gene carriers in the family. Additionally, genetic testing allows for the identification of family members who did not inherit the mutation and therefore do not warrant intensive surveillance programs. Coloseq™ is a comprehensive genetic test for the prediction and diagnosis of hereditary colon cancer that uses next generation sequencing to detect mutations in multiple genes associated with Lynch syndrome, FAP, and MUTYH-associated polyposis. Initially, the panel was developed to include seven genes that have a well-established role in clinical decision making for patients with Lynch or polyposis syndromes. Since then, however, the panel has undergone several evolutions to include four additional genes in June of 2012, two more genes in January of 2013 and, most recently, the addition of six genes in October of 2013. With a total of 19 genes now included, the panels utility has now expanded into the realms of endometrial, breast, and thyroid cancer, to name a few. Coloseq is not approved by the Food and Drug Administration (FDA) but clinical laboratories that develop and validate tests for in-house use are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

10/16/2013: MTAC REVIEW

Coloseq™ Colon Cancer Panel

Evidence Conclusion: *Analytic Validity* One publication from the Journal of Molecular Diagnostics was identified that addressed the analytic validity of ColoSeq™ (Pritchard, Smith et al. 2012). The study presents 99.4%-100% sensitivity and 99.4%-100% specificity. The paper was limited to the seven genes that were included on the original panel and thus does not provide sufficient evidence for the 19 gene panel that is currently used. No publications were identified that validated the entire 19 gene panel that has since evolved. *Clinical Validity* Pritchard and colleagues present that the clinical validity is achieved by targeting and validating only genes that, when mutated, are well-established causes of hereditary colon cancer leading to the conclusion that incorporating the results of the ColoSeq™ testing into clinical-decision making was now straightforward. The addition of new genes and inclusion of additional cancers compromise this claim. No publications were identified that addressed the clinical validity of the ColoSeq™ cancer panel. *Clinical Utility* Originally, the ColoSeq panel was designed to focus only on genes that have a well-established role in clinical decision making and patient management. The recent expansion of the ColoSeq panel compromises the overall clinical utility. No published literature addressed the clinical utility of the ColoSeq™ cancer panel.

Conclusion**:** There is insufficient evidence to determine the analytic validity, clinical utility and clinical validity of Coloseq™ for the identification of hereditary colon cancer.

Articles: A search of PubMed was completed for the period from April 2012 to November 5th, 2013 for studies on the accuracy of ColoSeq™ for detecting hereditary colon cancer. The search strategy used the terms *Coloseq™, genetic testing, Lynch syndrome, familial adenomatous polyposis (FAP), MUTYH-associated polyposis,* and *colon cancer* with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Selected articles were limited to those published in the English language enrolling human subjects. The search was supplemented by an examination of article reference

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lists in addition to the PubMed *related articles* function. **Screening of articles:** The literature search for ColoSeq™ revealed one July 2012 publication on the development and validity of the assay (Pritchard, Smith et al. 2012). Due to recent additions (October 2013) to the Coloseq™ cancer panel, this publication is no longer applicable and was not reviewed.

The use of Coloseq™ does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

***Note:** Codes listed in the criteria above may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

******To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
3/04/2014	3/04/2014[MPC], 6/3/2014[MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	11/15/2023

[MPC] Medical Policy Committee

Revision History	Description
06/30/2015	Added Medicare LCD links and PROOVE® panels.
08/27/2015	Added LCD 35850 and LCD 35504
09/08/2015	Revised LCD Circulating Tumor Cell Marker Assays LCD L35096 and L34066, Breast Cancer Genetic Assay L35500 and L36316, GeneSight® Assay for Refractory Depression L36324 and L36325, Genetic Testing L34101, LCD for ConfirmMDx Epigenetic Molecular Assay (L36328),
12/06/2016	Added Cx Bladder & My Risk Panel to the non-covered list
05/16/2017	Added Percepta LCD
06/15/2017	Added Invitae Stat Panel coverage
10/19/2017	Added Health Diagnostics to the non-covered panel list
03/26/2018	Added Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer
06/13/2018	Moved 81381 to the no review list
08/29/2018	Moved 81307 to no review at this time
06/02/2020	Added section: “Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees.” Requires 60-day notice, effective date 10/01/2020. Moved CPT codes 81402, 81403 and 81270 under Applicable Codes section that do not need review.
06/24/2020	Added CPT codes 0084U, 0085U, 0093U, 0094U, 0095U, 0097U, 0098U, 0099U, 0100U, 0101U, 0102U, 0103U, 0104U
07/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare. Requires 60-day notice, effective date 12/01/2020. Removed CPT codes that do not require review: 81220, 81221, 81240, 81241, 81261, 81340, 81341, 81342, 81372, 81374, 81375, 81376, 81377, 81378, 81379, 81380, 81381, 81402, 81403, 81270.
10/06/2020	Removed codes section; will defer to pre-authorization code check tool.
05/04/2021	Removed genetic panel tests that are no longer available. Updated Medicare LCD links and applicable codes.
09/27/2022	Added Prevention as a preferred lab vendor for genetic panel testing. Removed Caris and Oncoplex from the non-inclusive list of genetic panel tests. 60-day notice required; effective 03/01/2023.
01/19/2023	Removed Prolaris from the non-covered list. MPC approved to adopt criteria for Prostate Cancer Gene Expression Testing (Prolaris 81541) and Prostate Cancer (ConfirmMDx CPT 81551), effective 4/1/2023- see Genetic Screening Criteria for details.

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03/08/2023	Added Signatera to the non-covered panel list
05/15/2023	Updated Medicare Links including—newly retired policies L36163, L36329 and L36374
06/07/2023	Added Tempus xG Hereditary Cancer Panel test to the non-covered list.
11/15/2023	Added ProvSeq 523 test to the non-covered list

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